# EXHIBIT 7

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# **CONNETICS CORP**

3400 W BAYSHORE RD PALO ALTO, CA 94303 415. 843.2800

10-K/A

AMENDMENT TO FORM 10-K Filed on 07/25/2006 - Period: 12/31/2005 File Number 000-27406



# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

# Form 10-K/A Amendment No. 1

A	ANNUAL REPORT PURSUANT TO SEC OF 1934	TION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT
	For the Fiscal Year Ended December 31, 2005	
	,	OR
0	ACT OF 1934 For the Transition Period from to	SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE File Number: 0-27406
		CORPORATION trant as specified in its charter)
	Delaware	94-3173928
	(State or other jurisdiction of	(I.R.S. Employer
	incorporation or organization)	Identification No.)
	3160 Porter Drive,	94304
	Palo Alto, California	(Zip Code)
	(Address of principal executive offices)	
	Registrant's telephon	e number, including area code: 0) 843–2800
		rsuant to Section 12(b) of the Act: None
	Securities registered pu	rsuant to Section 12(g) of the Act:
		\$0.001 par value per share
		hare Purchase Rights
T 4: 1		itle of class)
Indicate by Yes □ No	check mark if the registrant is not required to file reports p	er, as defined in Rule 405 of the Securities Act. Yes \(\sim\) No \(\overline{\text{2}}\) arsuant to Section 13 or Section 15(d) of the Exchange Act.
during the pre-	ceding 12 months (or for such shorter period that the registr	equired to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 ant was required to file such reports) and (2) has been subject to such filing
Indicate by	for the past 90 days. Yes D No D refers pursuant to Ite	m 405 of Regulation S-K is not contained herein, and will not be contained, to the
this Annual Re	eport on Form 10–K/A. $\square$	nts incorporated by reference in Part III of this Form 10-K/A or any amendment to
Indicate by filer and large	check mark whether the registrant is a large accelerated file accelerated filer" in Rule 12b-2 of the Exchange Act.	er, an accelerated filer or a non-accelerated filer. See definition of "accelerated
	Large Accelerated Filer  Accel	erated Filer 🗹 Non-Accelerated Filer 🛘
Indicate by	check mark whether the registrant is a shell company (as d	efined in Rule 12b-2 of the Exchange Act). Yes □ No ☑

2004 and began selling the product in December 2004 in 50g and 100g trade unit sizes. Net product revenues for Evoclin Foam were \$24.8 million in 2005 and \$2.8 million for the fourth quarter of 2004. Evoclin Foam is contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin, a history of regional enteritis or ulcerative colitis, or a history of antibiotic—associated colitis.

PRODUCT CANDIDATES AND CLINICAL TRIALS

Our product candidates must go through extensive clinical evaluation and clearance by the FDA before we can sell them commercially. Our development model anticipates that we will conduct simultaneous studies on several products at a given time; however, we regularly re—evaluate our product development efforts. On the basis of these re—evaluations, we have in the past, and may in the future, abandon development efforts for particular products. Not all products or technologies under development will result in the successful introduction of a new product.

Desilux Foam

In September 2004, we commenced the Phase III clinical program for Desilux Foam, a low-potency topical steroid, formulated with 0.05% desonide in our proprietary emollient foam delivery vehicle. Desilux Foam is the first drug candidate for which we are seeking a pediatric label. The Phase III clinical program focused on atopic dermatitis, and on August 15, 2005, we announced the positive outcome of the clinical trial. The data from the trial demonstrate a consistently robust and highly statistically significant treatment effect for Desilux Foam compared to placebo foam on the primary trial composite endpoint evaluating improvement in the Investigator's Static Global Assessment, or ISGA, erythema and induration/papulation. The data from the trial also demonstrated that Desilux Foam was safe and well tolerated, with the most frequently observed side effects mild in nature and largely limited to application site reactions.

In November 2005, we submitted an NDA for Desilux Foam to the FDA. In January 2006, the FDA accepted the NDA for filing with a user fee goal date of September 21, 2006. We anticipate receiving FDA approval of Desilux Foam in September 2006.

Primelay Foam

In March and April, 2005, we commenced Phase III clinical trials to evaluate Primolux Foam, a super high-potency topical steroid, formulated with 0.05% clobetasol propionate in our proprietary emollient foam delivery vehicle, VersaFoam-EF(TM). The Primolux Foam clinical program consisted of two Phase III trials, one focusing on psoriasis and the other on atopic dermatitis. The psoriasis trial was completed with positive results in September 2005 and the atopic dermatitis trial was completed with positive results in November 2005. In both psoriasis and atopic dermatitis, Primolux Foam demonstrated significant positive results for all endpoints. We plan to submit an NDA to the FDA for Primolux Foam in the first quarter of 2006. Extina Foam

In April 2003, we announced summary results from our Phase III clinical trial with Extina Foam, a foam formulation of a 2% concentration of the antifungal drug ketoconazole for the treatment of seborrheic dermatitis. Ketoconazole is used to treat a variety of fungal infections, including seborrheic dermatitis, a chronic, recurrent skin condition. Industry sources estimate that seborrheic dermatitis affects 3–5% of the U.S. population. It usually involves the scalp, but also can affect the skin on other parts of

the body, including the face and chest. The symptoms of seborrheic dermatitis include itching, redness and scaling. In 2005 an estimated 1.1 million patients sought physician treatment for seborrheic dermatitis. Extina Foam is intended to compete primarily in the topical antifungal market, which industry sources estimate represented approximately \$735 million in U.S. prescriptions in 2005.

The Extina Foam clinical program consisted of a pivotal trial and two smaller supplemental clinical studies required by the FDA. As designed, the trial results demonstrated that Extina Foam was not inferior to Nizoral(R) (ketoconazole) 2% cream as measured by the primary endpoint of ISGA. The trial was also designed to compare Extina Foam to placebo foam per the ISGA. The result, although in favor of Extina Foam, did not achieve statistical significance. On all other endpoints, statistical significance was achieved; therefore, based on our belief that the totality of the data demonstrated that Extina Foam was clinically superior to placebo foam, we submitted an NDA to the FDA in July 2003.

In November 2004, the FDA issued a non-approvable letter for Extina Foam based on its conclusion that, although Extina Foam demonstrated non-inferiority to the comparator drug currently on the market, it did not demonstrate statistically significant superiority to placebo foam. Following continued discussions with the FDA, we recommenced development of Extina Foam by initiating a Phase III trial in September 2005 intended to demonstrate that Extina Foam is superior to placebo foam. Pending positive results from this Phase III trial, we expect to submit a Class 2 Resubmission for Extina Foam to the FDA by the end of 2006.

Velac Gel

In December 2002, we initiated a Phase III program for Velac Gel, a combination of 1% clindamycin and 0.025% tretinoin, for the treatment of acne. The Velac Gel clinical program consisted of two pivotal trials designed to demonstrate superiority to the individual drug products, and two smaller supplemental clinical studies required by the FDA. We completed enrollment of both pivotal trials in late 2003, enrolling over 2,200 patients, and announced in March 2004 the positive outcome of the Phase III clinical trials. The data from each trial demonstrated a statistically superior treatment effect for Velac Gel compared with clindamycin gel, tretinoin gel and placebo gel on both of the primary endpoints. An analysis of the combined data from the clinical trials demonstrated similar results to the individual trials. The data from these trials also demonstrated that Velac Gel was safe and well tolerated, with the most commonly observed adverse effects being application site reactions such as burning dryness, redness and peeling

with the most commonly observed adverse effects being application site reactions such as burning, dryness, redness and peeling.

We submitted an NDA to the FDA for Velac Gel in August 2004. The FDA accepted the NDA for filing in October 2004 with a user fee goal date of June 25, 2005. On June 10, 2005, the FDA issued a non-approvable letter for Velac Gel, citing that "a positive carcinogenicity signal was detected in a Tg.AC mouse dermal carcinogenicity study." Nothing in our clinical trials indicated that the mouse study was predictive of human results. We have been actively engaged in discussions with the FDA about the additional steps required to obtain approval of Velac Gel, and we continue to perform development

work related to the program.

Other Pipeline Formulations

In addition to the product candidates described above, we are developing foam technology for other disease indications. As part of our development model, we strive to have four product candidates in product formulation at any given time, so we have the flexibility in determining which two to move into human clinical trials. Our most promising preclinical candidates include an emulsion foam formulation of calcipotriene, a vitamin—D analog, for treatment of psoriasis; an aqueous foam formulation for the

combination of clindamycin and benzoyl peroxide in acne; and a topical formulation of acitretin (the active ingredient in Soriatane) for psoriasis. We are also exploring various product formulations for Liquipatch, which is described in more detail below under "Royalty-Bearing Products and Licensed ROYALTY-BEARING PRODUCTS AND LICENSED TECHNOLOGY

Foam Technology. We are a party to a license agreement with Pfizer, Inc. (formerly Pharmacia Corporation) pursuant to which we granted Pfizer Foam Technology. We are a party to a license agreement with Pfizer, Inc. (formerly Pharmacia Corporation) pursuant to which we granted Pfizer exclusive global rights, excluding Japan, to our proprietary foam drug delivery technology for use with Pfizer's Rogaine hair loss treatment. The license with Pfizer will expand the reach of the foam vehicle to the non-prescription (over-the-counter) pharmaceutical market. Under the agreement, Pfizer paid us an initial licensing fee, and agreed to pay us additional fees when it achieves specified milestones, plus a royalty on product sales. We recognized \$1.0 million under the agreement during 2002 related to license fees and milestone payments. During 2003, 2004 and 2005, we recognized \$86,000, \$11,000 and \$8,000, respectively, in license fees related to development costs. Pfizer is responsible for most product development activities and costs. Unless terminated earlier, the agreement with Pfizer will terminate on the first date on which all of Pfizer's obligations to pay royalties have expired or been terminated. In general, in each country (excluding Japan) where the manufacture, importation, distribution, marketing, sale or use of the product would infringe any of our issued patents covered by the agreement, Pfizer's obligation to pay patent royalties with respect to that country will expire automatically when the last of our patents to expire (or to be revoked) in that country excludily expires (or is expired). One U.S. patent has been issued covering the minoxidil foam technology, and we have additional applications pending in this field. In January 2006, Pfizer received approval from the FDA to sell its Rogaine hair loss treatment using our proprietary foam drug delivery technology in the U.S., and is obligated to pay us royalties on future product sales. Rogaine hair loss treatment using our proprietary foam drug delivery technology in the U.S., and is obligated to pay us royalties on future product sales.

Rogaine hair loss treatment using our proprietary foam drug delivery technology in the U.S., and is obligated to pay us royalties on future product sales. We are a party to a number of other agreements relating to foam technology. We have licensed the technology of betamethasone valerate foam to Celltech plc in Europe, and Celltech licensed the worldwide rights to their patent on the steroid foam technology to us. In 2003, we bought the rights to the U.S. patent from Celltech. In May 2004, Celltech was acquired by UCB Pharma, or UCB, a subsidiary of UCB Group. We pay UCB royalties on all sales worldwide of foam formulations containing steroids. UCB markets its product as Bettamousse(R) (the product equivalent of Luxíq), and UCB paid us royalties for its sales under the betamethasone valerate foam license through April 2003, at which time its royalty obligation under the contract ceased. We have license agreements with Bayer (in the U.S.) and Pfizer and Mipharm (internationally) for the use of pyrethrin foam for head lice. The head lice product is marketed as RID(R) in the U.S., as Banlice(R) in Australia, and as Milice(R) in Italy. We receive royalties on sales of those products. In February 2004, we entered into an agreement to license ketoconazole foam to Mipharm in exchange for an initial fee of \$90,000, plus future milestone and royalty payments. In 2004 and 2005, on a consolidated basis, we received \$244,000 and \$359,000, respectively, in royalties for foam-based technology.

As discussed above under "OLUX and Luxíq Foams," we licensed the commercial rights to Mipharm to market and sell OLUX Foam in Italy and the U.K., and we will receive milestone payments and royalties on future product sales. We have received \$309,000 under the agreement through December 31, 2005. Based on the minimum royalty provisions in the agreement and assuming the agreement stays in force through 2021, the aggregate potential minimum royalties under the contract are \$975,000. Unless terminated earlier, the agreement with Mipharm w

and the last expiration date of the patents covering the aerosol mousse technology, which is currently 2015. We have also granted exclusive commercial rights to Pierre Fabre to market and sell OLUX Foam in Europe, excluding Italy and the U.K., and certain countries in South America and Africa.

Genentech, Inc., and Amevive(TM), marketed by Biogen/ IDEC. Evoclin Foam competes primarily in the topical antibiotic acne market. Competition in this market includes generic and branded clindamycin and erythromycin, including branded products Clindagel marketed by Galderma S.A., Cleocin-T marketed by Pfizer, Inc., and Clindets marketed by Stiefel Laboratories, Inc. Generic and branded combinations of clindamycin and benzoyl peroxide, such as Benzaclin marketed by Dermik and Duac marketed by Stiefel, and erythromycin and benzoyl peroxide, such as Benzamycin marketed by Dermik, also present competition for Évoclin Foam.

Many of our existing or potential competitors, particularly large pharmaceutical companies, have substantially greater financial, marketing, sales, technical and human resources than we do. Furthermore, many of our competitors are private companies or divisions of much larger companies that do not have the same disclosure obligations regarding their product development and marketing strategies and plans that we do as a public company, which puts us at a distinct competitive disadvantage relative to these competitors. Our products could be rendered obsolete or made uneconomical by the development of new products to treat the conditions addressed by our products, technological advances affecting the cost of production, or marketing or pricing actions by one or more of our competitors.

CUSTOMERS

We sell our products directly to distributors, who in turn sell the products into the retail marketplace. Our customers include the nation's leading wholesale pharmaceutical distributors, such as Cardinal Health, Inc., McKesson Corporation, and AmerisourceBergen Corporation. Walgreens, a national retail pharmacy chain, was also one of our customers until January 2006 when it began purchasing our products directly from a distributor. We entered into a distribution agreement with each of Cardinal Health, Inc. and McKesson Corporation in December 2004 and with AmerisourceBergen in September 2005 under which we agreed to pay a fee to each of these distributors in exchange for certain product distribution, inventory information, return goods processing, and administrative services. While these agreements provide us with inventory level reports from these distributors, we must also rely on historica prescription information to estimate future demand for our products and to estimate the amount of reserves for rebates, chargebacks, and returns. During 2005, McKesson, Cardinal, and AmerisourceBergen accounted for 36%, 34%, and 11%, respectively, of our net product revenues. RESEARCH AND DEVELOPMENT AND PRODUCT PIPELINE

Innovation by our research and development operations contributes to the success of our business. Our research and development expenses were \$31.9 million in 2005, \$21.5 million in 2004, and \$30.1 million in 2003. Our goal is to develop and bring to market innovative products that address unmet healthcare needs. Our substantial investment in research and development and our active in-licensing strategy both support this goal.

Our development activities involve work related to product formulation, preclinical and clinical study coordination, regulatory administration, manufacturing, and quality control and assurance. Unlike many pharmaceutical companies that conduct early stage research and drug discovery, we focus on later-stage development. We believe this approach helps to minimize the risk and time requirements for us to get a product on the market. Our strategy involves targeting product candidates we believe have attractive market potential, and then rapidly evaluating and formulating new therapeutics by using previously approved active ingredients reformulated in our proprietary delivery system. This product development strategy allows us to conduct limited preclinical safety trials, and to move rapidly into safety and efficacy testing in humans with products that offer significant improvements over existing products. A secondary strategy we pursue is to evaluate the acquisition of products from other companies. products. A secondary strategy we pursue is to evaluate the acquisition of products from other companies.

#### **GOVERNMENT REGULATION**

Generally—Product Development. The pharmaceutical industry is subject to regulation by the FDA under the Food, Drug and Cosmetic Act, by the states under state food and drug laws, and by similar agencies outside of the United States. In order to clinically test, manufacture, and market products for therapeutic use, we must satisfy mandatory procedures and safety and effectiveness standards established by various regulatory bodies. A more detailed explanation of the standards we are subject to is provided under "Risk Factors — We may spend a significant amount of money to obtain FDA and other regulatory approvals, which may never be granted" and "—We cannot sell our current products and product candidates if we do not obtain and maintain governmental approvals" below.

regulatory approvals, which may never be granted and — we cannot sett our current products and product canadates, we do not contain and managemental approvals. Below.

All of our prescription pharmaceutical products will require regulatory approval by governmental agencies before they can be commercialized. The nature and extent of the review process for our potential products will vary depending on the regulatory categorization of particular products. Federal, state, and international regulatory bodies govern or influence, among other things, the testing, manufacture, labeling, storage, record keeping, approval, advertising, and promotion of our products on a product—by—product basis. Failure to comply with applicable requirements can result in warning letters, fines, injunctions, penalties, recall or seizure of products, total or partial suspension of production, denial or withdrawal of approval, and civil or criminal prosecution. Accordingly, initial and ongoing regulation by governmental entities in the U.S. and other countries is a significant factor in the production and marketing of any pharmaceutical products that we have or may develop.

Product development and approval within this regulatory framework, and the subsequent compliance with appropriate federal and foreign statutes and

regulations, takes a number of years and involves the expenditure of substantial resources. FDA Approval. The general process for approval by the FDA is as follows:

- FDA Approval. The general process for approval by the FDA is as follows:

  Preclinical Testing. Generally, a company must conduct preclinical studies before it can obtain FDA approval for a new therapeutic agent. The basic purpose of preclinical investigation is to gather enough evidence on a potential new agent through laboratory and animal testing to demonstrate there is a reasonable enough expectation of efficacy to justify exposing humans to the risk of adverse events associated with any new drug, and to demonstrate there are no safety signals that would suggest it would not be prudent to begin preliminary trials in humans. The sponsor of these studies submits the results to the FDA as a part of an investigational new drug application, or IND, that the FDA must review before human clinical trials of an investigational drug can start. FDA approval of new drug candidates requires an adequate demonstration of safety and efficacy in man. For each investigational product entering clinical trials, we are required to file an IND and perform our clinical studies to IND standards set by the FDA.
- Clinical Trials. Clinical trials are normally done in three distinct phases and generally take two to five years, but may take longer, to complete:
   Phase I trials generally involve administration of a product to a small number of patients to determine safety, tolerance and the metabolic and pharmacologic actions of the agent in humans and the side effects associated with increasing doses.
  - Phase II trials generally involve administration of a product to a larger group of patients with a particular disease to obtain evidence of the agent's
    effectiveness against the targeted disease, to further explore risk and side effect issues, and to confirm preliminary

data regarding optimal dosage ranges.

• Phase III trials involve more patients, and often more locations and clinical investigators than the earlier trials. At least one such trial is required for FDA approval to market a branded, or non-generic, drug.

The rate of completion of our clinical trials depends upon, among other factors, the rate at which patients enroll in the study. Patient enrollment is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the eligibility criteria for the study, and the sometimes seasonal nature of certain dermatological conditions. Delays in planned patient enrollment may result in increased costs and delays, which could have a material adverse effect on our business. In addition, side effects or adverse events that are reported

during clinical trials can delay, impede, or prevent marketing approval.

Regulatory Submissions. The Food, Drug and Cosmetic Act outlines the process by which a company can request approval to commercialize a new product. After we complete the clinical trials of a new drug product, we must file an NDA with the FDA. We used the so-called 505(b)(2) application process for OLUX, Luxíq, and Evoclin, which permitted us in each case to satisfy the requirements for a full NDA by relying on published studies or the FDA's findings of safety and effectiveness based on studies in a previously-approved NDA sponsored by another applicant, together with the studies generated on our products. If studies previously submitted by another applicant and relied upon as part of 505(b)(2) application are found by the FDA not to be up to contemporary standards, it may be necessary to repeat them. The FDA may also require 505(b)(2) applicants to provide additional safety data that was not required at the time of the original application. Generally, however, the number of clinical trials required to support a 505(b)(2) application and the amount of information in the application itself may be substantially less than that required to support a traditional NDA. application, and the amount of information in the application itself, may be substantially less than that required to support a traditional NDA application. The 505(b)(2) process will not be available for all of our other product candidates, and as a result the drug development process may be longer for our future product candidates than it has been for our products to date. The FDA may also require an applicant to conduct post-approval studies or implement risk management programs that do not delay market entry but do increase product-related research and development costs.

studies or implement risk management programs that do not delay market entry but do increase product—related research and development costs.

We must receive FDA clearance before we can commercialize any product, and the FDA may not grant approval on a timely basis or at all. The FDA can take between one and two years to review an NDA, and can take longer if significant questions arise during the review process. In addition, if there are changes in FDA policy while we are in product development, we may encounter delays or rejections that we did not anticipate when we submitted the NDA for that product. We may not obtain regulatory approval for any products that we develop, even after committing such time and expenditures to the process. Even if regulatory approval of a product is granted, it may entail limitations on the indicated uses for which the product may be marketed.

\*\*Manufacturing\*\* The FDA regulates and inspects equipment, facilities, and processes used to manufacture pharmaceutical products before providing approval to market a product. If we make a material change in manufacturing equipment, location, or process, we may have to undergo additional regulatory review. We and our contract manufacturers must adhere to GMP and product-specific regulations enforced by the FDA. The FDA also conducts regular, periodic visits to re-inspect equipment, facilities, and processes after the initial approval. If the FDA determines that our (or our contract manufacturers') equipment, facilities, or processes do not comply with applicable FDA regulations and conditions for product approval, the FDA may seek sanctions and/or remedies against us, including suspension of our manufacturing operations.

products. This in turn could cause a loss of our market share and negatively affect our revenues. Numerous factors could cause interruptions in the supply of our finished products, including shortages in raw material required by our manufacturers, changes in our sources for manufacturing, our failure to timely locate and obtain replacement manufacturers as needed, and conditions affecting the cost and availability of raw materials. Orders for our products may decrease depending on the inventory levels held by our major customers. Significant changes in orders from our major

customers could cause our operating results to vary significantly from quarter to quarter.

Retail availability of our products is greatly affected by the inventory levels our customers hold. We monitor wholesaler inventory of our products using a combination of methods, including information provided by the customers as well as tracking prescriptions filled at the pharmacy level to determine amounts the wholesalers have sold to their customers. Pursuant to our distribution service agreements with Cardinal, McKesson and AmerisourceBergen we receive inventory level reports, but until December 2005 the reports we received contained inaccuracies and inconsistencies that made them unreliable. Based on reporting in December 2005, we concluded that our product inventory at those wholesalers was higher than previously estimated. For other wholesalers that do not provide us with inventory level reports, our estimates may differ significantly from actual inventory levels. Significant differences between actual and estimated inventory levels or reporting inaccuracies from the wholesalers may result in excessive inventory production, excess product available at the retail level, and unexpected increases or decreases in orders from our major customers. These changes may cause our net revenues to fluctuate significantly from quarter to quarter, and in some cases may cause our operating results for a particular quarter to be below our expectations or projections. If our financial results are below expectations for a particular period, the market price of our securities may drop significantly. See also "Risk Factors Related to Our Business – Our decision to reduce wholesale inventory could decrease our product revenue. We cannot sell our current products and product candidates if we do not obtain and maintain governmental approvals.

Pharmaceutical companies are subject to heavy regulation by a number of national, state and local agencies. Of particular importance is the FDA. The FDA has jurisdiction over all of our business and administers requirements covering testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our products. If we fail to comply with applicable regulatory requirements, we could be subject to fines, suspensions of regulatory approvals of products, product recalls, delays in product distribution, marketing and sale, and civil or criminal sanctions.

suspensions of regulatory approvals of products, product recalls, delays in product distribution, marketing and sale, and civil or criminal sanctions.

The process of obtaining and maintaining regulatory approvals for pharmaceutical products, and obtaining and maintaining regulatory approvals to market these products for new indications, is lengthy, expensive and uncertain. The manufacturing and marketing of drugs, including our products, are subject to continuing FDA and foreign regulatory review, and later discovery of previously unknown problems with a product, manufacturing process or facility may result in restrictions, including recall or withdrawal of the product from the market. The FDA is permitted to revisit and change its prior determinations and it may change its position with regard to the safety or effectiveness of our products. Even before any formal regulatory action, we could voluntarily decide to cease distribution and sale or recall any of our products if concerns about safety or effectiveness develop.

In its regulation of advertising, the FDA from time to time issues correspondence to pharmaceutical companies alleging that some advertising or promotional practices are false, misleading or

promotional practices are false, misleading or

deceptive. The FDA has the power to impose a wide array of sanctions on companies for such advertising practices, and if we were to receive correspondence from the FDA alleging these practices we might be required to:
• change our methods of marketing and selling products,

- take FDA-mandated corrective action, which could include placing advertisements or sending letters to physicians rescinding previous advertisements or promotion.
- incur substantial expenses, including fines, penalties, legal fees and costs to comply with the FDA's requirements,

disrupt the distribution of products and stop sales until we are in compliance with the FDA's position.

We may spend a significant amount of money to obtain FDA and other regulatory approvals, which may never be granted. Failure to obtain such regulatory

approvals could adversely affect our prospects for future revenue growth.

Successful product development in our industry is highly uncertain, and the process of obtaining FDA and other regulatory approvals is lengthy and Successful product development in our industry is highly uncertain, and the process of obtaining FDA and other regulatory approvals is lengthy and expensive. Very few research and development projects produce a commercial product. Product candidates that appear promising in the early phases of development may fail to reach the market for a number of reasons, including that the product candidate did not demonstrate acceptable clinical trial results in humans even though it demonstrated positive preclinical trial results, or that the product candidate was not effective in treating a specified condition or illness. The FDA may also require additional clinical data to support approval. The FDA can take between one and two years to review new drug applications, or longer if significant questions arise during the review process. Moreover, the costs to obtain approvals could be considerable and the failure to obtain, or delays in obtaining, an approval could have a significant negative effect on our business. For example, in November 2004, the FDA notified us that it would not approve our NDA for Extina Foam based on its conclusion that, although Extina Foam demonstrated non-inferiority to the comparator drug currently on the market it did not demonstrate statistically significant superiority to placeho foam. In addition, on lune 10, 2005, the FDA issued as drug currently on the market, it did not demonstrate statistically significant superiority to placebo foam. In addition, on June 10, 2005, the FDA issued a non-approvable letter for Velac Gel, citing that "a positive carcinogenicity signal was detected in a Tg.AC mouse dermal carcinogenicity study." We depend on a limited number of customers, and if we lose any of them, our business could be harmed.

Our customers include the nation's leading wholesale pharmaceutical distributors, such as Cardinal Health, Inc., McKesson, Corporation, and

AmerisourceBergen Corporation. During 2005, McKesson, Cardinal, AmerisourceBergen accounted for 36%, 34%, and 11%, respectively, of our net product revenues. The distribution network for pharmaceutical products is subject to increasing consolidation, and a few large wholesale distributors control a significant share of the market. In addition, the number of independent drug stores and small chains has decreased as retail consolidation has occurred. Further consolidation among, or any financial difficulties of, distributors or retailers could result in the combination or elimination of warehouses, which may result in reductions in purchases of our products, returns of our products, or cause a reduction in the inventory levels of distributors and retailers, any of which could have a material adverse impact on our business. If we lose any of these customer accounts, or if our relationship with them were to deteriorate,

our business could also be materially and adversely affected.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and Analysis of Financial Common and Results of Operations

The following discussion should be read in conjunction with our Consolidated Financial Statements and related Notes to Consolidated Financial

Statements contained elsewhere in filed with this Annual Report on Form 10–K/A. Except as discussed above, we have not modified or updated disclosures presented in the original Annual Report on Form 10–K/A, filed on March 13, 2006, other than as required to reflect the effects of the restatement. As such, this Annual Report on Form 10–K/A does not reflect events that occurred after we filed our original Annual Report on Form 10–K and does not modify or update those disclosures affected by subsequent events, except as specifically referenced in the disclosures. We have made no changes to information not affected by the restatement, and therefore we have omitted all such unchanged information that reflects the disclosures made at the time of the original filling of the Annual Report on Form 10-K.

As announced in our Current Report on Form 8-K filed on May 3, 2006, after we filed our Original 10-K, we concluded that our previously filed consolidated financial statements should no longer be relied upon due to errors in the accounting for accruals for estimated rebates and chargebacks for our products. Because we were already examining revenue reserves in prior years, management decided to apply the same resources to evaluate how we estimate accruals for returns of our products. As a result of our evaluation, we determined that our methodology for estimating future product returns had contained errors and resulted in an understatement of our returns accruals. We also recorded certain other immaterial adjustments associated with the revenue reserve adjustments. Note 2 of Notes to the Consolidated Financial Statements details the adjustments made to historical data as of December 31, 2005 and 2004 and for each of the three years in the period ended December 31, 2005.

Rebates are contractual discounts offered to government programs and private health plans that are eligible for such discounts at the time prescriptions are dispensed, subject to various conditions. Chargebacks represent discounts that our wholesale customers charge us for the difference between the then-current retail price and the lower price they are paid by certain government entities who are entitled to discounts under contracts with us. We record provisions for rebates and chargebacks by estimating these liabilities as products are sold, based on factors such as timing and terms of plans under contract, time to process rebates, product pricing, sales volumes, amount of inventory in the distribution channel, and prescription trends. As part of our procedures to prepare for the closing of the first quarter of 2006 financial statements, during March and April 2006, we revised our accounting process for estimating revenue-related reserves, including rebates and chargebacks. As part of this process, we determined that our rebate and chargeback accruals had not been adequately capturing the full liability associated with the amount of product inventory in the distribution channel. We concluded that the impact of the revised methodology required us to restate our financial statements. revised methodology required us to restate our financial statements.

Our revised rebate and chargeback methodology is intended to fully capture our liability for (1) incurred-but-uninvoiced rebates and unprocessed chargebacks, and (2) future rebate and chargebacks associated with product inventory held in the distribution channel at period end, as required by U.S. generally accepted accounting principles. Our revised methodology also addresses factors such as anticipated price increases on our products and estimated future usage of our products by Medicaid programs and managed care organizations.

We have also determined that our prior methodology for estimating future product returns contained

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errors and resulted in an understatement of our returns accrual. Previously, we estimated the return rate based on our cumulative historical return experience with related units shipped since initial sale and other relevant qualitative factors. For two of our products, OLUX and Luxíq, we applied the estimated return rate to the units in the distribution channel at period end, which was a smaller population than all units with potential risk of return. For our other two products, Soriatane and Evoclin, we calculated the value of the estimated units to be returned using the original sales price without taking into account price increases which were implemented between the date of sale through the period of the accrual. We permit wholesalers to return expired or expiring product for a credit at the then—current sales price less 5%, so the initial sales price may not fully capture our liability for future returns. As a result of our evaluation, we determined that our accruals for product returns had been understated. Our revised methodology estimates the return rate on the most recent three years' data, resulting in an estimated rate that is more responsive to current return trends. We assess the risk of return on a production lot basis and apply our estimated return rate to the units at risk for return.

Immaterial Adjustments

In addition, because we have restated for these items, we have recorded certain immaterial adjustments as of December 31, 2005 and 2004 and for each of the three years in the period ended December 31, 2005.

Impact of Restatement

As a result of our analysis of rebate and chargeback accruals and accruals for returns of our products, we have restated our consolidated financial statements for each of the five years in the period ended December 31, 2005 The increased accrual for estimated rebates and chargebacks had the cumulative effect of decreasing net product revenues by \$7.4 million through December 31, 2005; the increased accrual for estimated returns had the cumulative effect of decreasing net product revenues by \$3.7 million through December 31, 2005. The table below sets forth the income statement impact of the increased accrual for estimated rebates and chargebacks and accruals for product returns for each of the five years in the period ended December 31, 2005 (in thousands):

	Ker	oates and			
Year ended December 31,		rgebacks		eturns	Total
	***	250	42.21 <b>3</b>	363	\$ 613
2002 2003		431 643 V		847 509	1,278 167
2004 2005		CALL THE PROPERTY OF THE PARTY		916 931	1,137 7,895
Total	\$	7,435	\$	3,655	\$ 11,090
44					

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Connetics Corporation a Delaware corporation

/s/ John L. Higgins

John L. Higgins Chief Financial Officer Executive Vice President, Finance and Corporate Development

Date: July 24, 2006

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The tables below set forth the effect of the adjustments for the four quarters in the year ended December 31, 2005:

	Three Mo	nths Ended March 3	1, 2005	Three M	onths Ended June 30	, 2005
		(unaudited)			(unaudited)	
	As Previously Reported	Revenue Reserve Adjustments	As Restated	As Previously Reported	Revenue Reserve Adjustments	As <u>Restated</u>
Net product revenues: Soriatane OLUX Foam Eyoclin Foam Eurof Foam Other	\$ 17.581 18,792 3,067 5,654 96	(a) \$ (1,217) (808) (27) (27)	\$ 16,364 14,984 3,040 5,721 96	\$ 18,334 14,033 7,037 5,885	(b) \$ (591) 388 (270) (70)	\$ 17,743 \$ 17,743 6,958 6,224
Total net product revenues Royalty and contract revenues	42 <u>19</u> 4	(12985)	40,205 181	43,239 [1]		- 35,338 130
Operating costs and expenses	42,371 40,872	(1985)	40,386 40,872	45,369 42,695		<b>45,468</b> 42,695
income closs from operations. Interest and other income (expense), net	1,499 (353)	(1,985)	<b>(486)</b> (353)	<b>2,674</b> (19)		<b>2,773</b> (19)
income (loss) before income for taxes  Income tax provision (benefit)	1146	(1,985)	(839) 105	<b>新聞養</b>	9947.	2,754 153
Net income (loss)	<b>3</b> 13,01	\$ (1,985)	\$ (944)	\$ 2,502	\$## £1.2%.99	\$ 2,601
Net income (loss) per share: Basic	\$ 0.03		\$ (0.03)	\$ 2007		\$ 0.07
Diluted	\$ 0.03		\$ (0.03)	\$ 0.07		\$ 0.07
Shares used to compute basic and diluted net income (loss) per share: Basic	35,699		35,699	34.825		.5.54445.8 34.825
Diluted 2.4.28%.	38,0 <b>14</b>	的多种种类的现在形式	35,699	37,093		37,093
(a)			2005 in	venue reserves adjust actudes \$665,000 for 3 million for returns.	ment for the period en rebate and chargeback	led March 31, adjustments
(b)			2005 in	icludes a decrease of nents partially offset	ment for the period en \$200,000 for rebate ar by an increase of \$101	d chargeback
		F-11				

	Thr	ee Months Ended S	September 30, 2	2005	Three Month	s Ended December :	31, 2005	
		(unaudi				(unaudited)		
	As Previously Reported	Revenue Reserve Adjustments	As Restated	As Previously <u>Reported</u>	Revenue Reserve Adjustments	Other Adjustments	As <u>Restated</u>	
Net product revenues:		(a)			<b>(b)</b>			
Soriatane OLUX Foam	\$ 23.077 17.323	\$ (2,273)	\$ 20,804 15,879	\$ 13,603 14,646	\$ 1,350 ****(1913)**		\$ 14,953 12,733	
Evoclin Foam	7,724 7,014	(205) (473)	7,519 6,5 <b>41</b>	6,851 5,599	415 ( <b>1,466</b> )		7,266 4,133	
Other	45	_	45	1	_	_	1	
Total net product	55,183	(4,395)	50,788	40,700	(1,614)		39,086	
Royalty and contract revenues	158	_	158	483	_	_	483	
Total net	55,341	(4,395)	50,946	d <b>5441,183</b>	14 (1,614)		39;569	
Operating costs and expenses	39,666	_	39,666	37,134	-	4	37,138	
Income (loss) from (perations	15.675	(4.395)	11,280		1,614)		2.431	
Interest and other income (expense), net	160	_	160	413	<u> </u>	<u> </u>	413	
Income (loss) before income taxes	15,835	(4,395)	11,440	4,462	( <b>7,614</b> )	(4)	2844	
Income tax provision (benefit)	470	_	470	(10,588)	<del></del>	(62)	(10,650)	
Net income (loss)	\$ 15,365 .	\$ = (4,395)	\$ 10,970	\$ 15,050	\$ (F,614)	(1) \$ 11 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	\$ 13,494	
Net income (loss) per share:			\$ 031	\$ 044	on the state of the		8 <b>3</b> - 030	
Harris and the state of the sta			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				and the second s	
Diluted	\$ 0.39		\$ 0.29	\$ 0.40			\$ 0.36	
Shares used to compute basic and diluted net income (loss) per share								
Basic Dilued	35,075 40,812	MINIMUM NUMBER	35,075 <b>40,812</b>	34,570 39,735	44 A		34,570 39,735	
(a)				Septeml	enue reserves adjustm ber 30, 2005 includes ack adjustments and S	\$3.9 million for rebat		
(b)				Decemb chargeb	enue reserves adjustm er 31, 2005 includes ack adjustments, part 10 for returns.	\$2.6 million for rebat	e and	
(c)				represer	tax provision (benefit ats the tax effect of the	t) – The adjustment of adjustments.	f \$62,000	
The table below sets forth	the effect of the a	diustments on the ba	alance sheet as	of December 31, 2	2004:			

The table below sets forth the effect of the adjustments on the balance sheet as of December 31, 2004:

		December 31	, 2004	
	As Previously	Revenue Reserve	Other	As
	Reported	Adjustments	Adjustments	Restated
Accounts receivable, net of cash discounts and allowances of \$708 (a)	\$ 28,191	\$ m	<b>*\$</b>	\$ 28,191
Other current assets  Long-term assets	87,927 147,159	511976 E.E.E.E.E.E.E.E.E.E.E.E.E.E.E.E.E.E.E.	20 3. 金老 <del>红</del> 纸纸	87,947 147,159
Total assets	263,277	_	20	263,297
Product-related accinals (a) (b) (c)	18.426	3.195		21.621
Other current liabilities (c) Long-term liabilities	26,511 90,420		(147)	
Total liabilities Accumulated deficits	135,357	3,195	(147) Basis 167	138,405
Accumulated deficits Other stockholders' equity	(111,173) 239,093	(3,195)	167 — 167 —	(114,201) 239,093
Total stockholders' equity	127,920	(3,195)	167	124,892

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Total liabilities and stockholders' equity

\$ 263,277

\$

\_\_\_

20

\$ 263,297

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## **Table of Contents**

(a)	Accruals for product returns and chargebacks were previously netted against accounts receivable and have been reclassified to product—related accruals.
(b)	Product-related accruals — the adjustment of \$3.2 million represents \$471,000 million related to an increase in our rebates and chargebacks reserves and \$2.7 million related to an increase in our returns reserve.
(c)	Accruals for payments due to wholesalers under distribution

Accruals for payments due to wholesalers under distribution service agreements that were previously included as other accrued liabilities have been reclassified to product-related

accruals.

The table below sets forth the effect of the adjustments on the Consolidated Statement of Operations for the year ended December 31, 2004:

	Year Ended December 31, 2004						
2. C. Takanga ang kanalang ang	As Prev Repor		Res	enue serve stments	Oth <u>Adjust</u>		As Restated
Net revenues: Product (a) Royalty and contract	\$ 1 <sub>4</sub>	12,059 <b>2,296</b>	\$ 	(1.137)	\$ \$ }7. [25]		\$140.922 2,296
Total net revenues  Operating costs and expenses	14 15 42	14,355 22,372		(1,137)	110×	( <del>3</del> 3)	143,218 122,339
Income (loss) from operations Interest and other income (expense), net		21,983 ( <b>1,475</b> )	reti	(1.137) (1.137)	84.	33	20,879 (1, <b>475</b> )
Income (loss) before income taxes Income tax provision (benefit) (b)		20,508 1,493		(1.137) (1.137)		33 (24)	19,404 1 <b>,46</b> 9
Net income (loss)	<b>\$</b> 1	19,015	\$	(1,137)	· \$	57	\$ 17,935
Net income (loss) per shares. The last is a last income (loss) per shares.	\$	0.54					\$ 0.51
Diluted	\$ 4.5	051	alesand		i Brazilia		\$ 0.48
Shares used to compute basic and diluted net income (loss) per share:  Basic	F 12	<b>15</b> ,036			e pře		25,036
Diluted	3	37,443					37,443
(a)		represe related \$916,00	nts an in to an inc 00 relate	d to an increa	revenue re rebates and ase in our re	eserves of \$2 I chargeback eturns reserv	221,000 as reserve and we.
(b)				vision (benef ux effect of th			\$24,000
F	<del>-</del> 13						

The tables below set forth the effect of the adjustments for the four quarters in the year ended December 31, 2004:

	Three Monti	ns Ended March 31, (unaudited)	, 2004	Three I	Three Months Ended June 30, 2004 (unaudited)			
	As Previously Reported	Revenue Reserve Adjustments	As <u>Restated</u>	As Previously Reported	Revenue Reserve Adjustments	As Restated		
Net product revenues: Soriatane OLUX Foam Luxiq Foam Other	\$ 3,640 \$ 12,570 \$ 471 85	(a) \$ (8) (397) (18)	\$ 3,632 13,973 5,453 85	\$ 17,154 15,223 5,614 8	(b) \$ (136) .883 .287	\$ 17,018 - 15,309 - 6,061 8		
Total net product revenues Royalty and contract	23,566 1,416	(423) —	23,143 = 1,416	37,999 254	-	38,396 254		
Total net revenues Operating costs and expenses	2 <b>4,982</b> 22,574	(423) <sup>1</sup>	2 <b>4,559</b> 4. 22,574	29,541	445 397	3 <b>8,650</b> 29,541		
Income (loss) from operations Interest and other income (expense), net	12,408 (292)	(423)	1,985 (292)	** :::::::::::::::::::::::::::::::::::	397	9,109		
Income (loss) before mound	2,116	(423)	1,693	8,104	397	8,501c		
(benefit)  Net income (loss)	243 \$ 1,873		243 \$ 1,450	647 <b>5</b> 7,457	— ************************************	647 \$ 7,854		
Net income (loss) per share:	\$20.06		**************************************	# <b>\$</b>    1 0.21		\$ 022		
Diluted	\$ 0.05		\$ 0.04	\$ 0.19		\$ 0.21		
Shares used to compute basic and dithred net income (loss) per share: Basic Diluted	33,587 33,887		33.587 - 35.887	35,242 41,627		35,242 41,627		
(a)			2004	revenue reserves ad includes \$203,000 \$220,000 for returns	iustment for the period end for rebate and chargeback	ded March 31, adjustments		
<b>(b)</b>			2004	includes \$249,000 includes	justment for the period end for returns, offset by a \$64 d chargeback liability.	ded June 30, 46,000		
		F-1	4					

	Three Months Ended September 30, 2004			Three Months Ended December 31, 2004				
		(unaudited)			(unaudited)			
	As Previously Reported	Revenue Reserve Adjustments	As Restated	As Previously Reported	Revenue Reserve Adjustments	Other Adjustments	As Restated	
Net product revenues: Soriatane OLUX Foam Evoclin Foam Luxiq Foam Other	\$ 14,724 15,962 	\$ 130 (250) (96)	\$ 14.854 15,712 	\$ 18,049 16,339 2,883 6,216	(b) \$ (91) (600) (45) (159)		\$ 17,958 15,739 2,838 6,057 8	
Total net mines product product Royalty and contract revenues	36,999 in 6	(216)	36,783		( <b>788)</b>		<b>42,600</b> 281	
Total net revenues  Operating costs and	97,344	(216)	37/128	201 201 201 201 201 201 201 201 201 201	(895)	And the same	42,881	
expenses	33,132	_	33,132	37,125	_	(33)	37,092	
fissone  Closs from  operations  Interest and other		(216)	3,996	(1) (1) (1) (1) (1) (1) (1) (1) (1) (1)	(895)	7.29	5,789	
income (expense), net	(373)	<del>-</del>	(373)	(202)	_	_	(202)	
income (loss) before income taxes Income tax provision	18. 18. 18. 18. 18. 18. 18. 18. 18. 18. 18.	(216)	·	•	(895)		5,587	
(benefit)	144		144	459		(24)	435	
Net income (loss)	\$ 3,695	\$ (216)	<b>\$</b> 3,479	J \$11   5,990 i i	\$ (895)	3: <b>\$</b> 5:1111:12-57	\$ 5,152	
Net income (loss) per share: Basic	<b>/\$</b> {\:\:\:\:\:\\\\\\\\\\\\\\\\\\\\\\\\\\\		\$ 0.10	<b>* \$ - 0.17</b> = \$			\$ 0.14	
Diluted	\$ 0.10		\$ 0.09	\$ 0.16			\$ 0.13	
Shares used to compute basic and diluted net income (foss) per shares. Basic	35,510 38,064		35,510 38,064	35,695 38,172			35,695 38,172	
(a)				September	e reserves adjustme 30, 2004 includes \$ s and \$19,000 for re	nt for the period end 197,000 for rebate ar turns.	ed ad	
(b)				December 3		nt for the period end 167,000 for rebate ar 28,000 for returns.		

December 31, 2005 includes \$467,000 for rebate and chargeback adjustments and \$428,000 for returns.

The table below sets forth the effect of the adjustments on the Consolidated Statement of Operations for the year ended December 31, 2003:

		Year	Ended December 3	1, 2003	!
			Revenue		
	_ A		Reserve	Other	_ As _
The second control of	Previously		<u>Adjustments</u>	<u>Adjustments</u>	Restated
Net revenues: *** Extra ************************************					
Product (a) Royally and contract		66,606 1.8,725	\$ (167)		\$_66,439 
		1			
Total net revenues Operating costs and expenses		75,331 <b>77,838</b>	(167) 	(76)	75,164 77,7 <b>62</b>
Y		(0.50T)	(1(7)	76	(2.508)
Income (loss) from operations Interest and other medime (expense), net		(426)			(426)
1 (1		(2.022)	(167)	76	(2.024)
Income (loss) before income taxes Income tax provision (benefit) (b)		1,167		.76 (34)	1,133
Not in a room (local)	<b>e</b> r	(4.100)	¢ (167)	¢ 110	¢ (4.157)
Net income (loss)	Ф	(4,100)	\$ (167)	\$ 110	\$ (4,157)
Net income (loss) peeshare:					

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Basic		\$	(0.13)	\$ (0.13)
Diluted			. (0.13)	\$ (0.05)
	to compute basic and diluted net income (l		31.559	
Diluted			31,559	31,559
		F-15		

# EXHIBIT 8

# **CONNETICS CORP**

3400 W BAYSHORE RD PALO ALTO, CA 94303 415. 843.2800

8-K

FORM 8-K Filed on 05/24/2002 - Period: 05/14/2002 File Number 000-27406



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# SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

### FORM 8–K CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

May 14, 2002

(Date of earliest event reported) CONNETICS CORPORATION

(Exact name of Registrant as specified in its charter)

Delaware	0–27406	94–3173928
(State or Other Jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)
_	3290 West Bayshore Road, Palo Alto, California 94303	
	(Address of principal executive offices, including zip code) (650) 843-2800	
•	(Registrant's telephone number, including area code)	_

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Item 5. Other Events.
Item 7. Financial Statements, ProForma Financial Information and Exhibits.
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EXHIBIT INDEX
EXHIBIT 99.1

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Item 5. Other Events.

On May 14, 2002, Connetics Corporation entered into a license and development agreement with Yamanouchi Europe B.V. pursuant to which Connetics has licensed Velac® gel (a combination of 1% clindamycin and 0.025% tretinoin) from Yamanouchi Europe B.V. Under the terms of the license agreement, Connetics will pay Yamanouchi an initial licensing fee, milestone payments and a royalty on product sales. Connetics will be responsible for most product

development activities and costs.

A copy of the press release announcing this transaction is attached to this Report as Exhibit 99.1 and is incorporated into this report by this reference.

Item 7. Financial Statements, ProForma Financial Information and Exhibits.

- (c) Exhibits.
  - 99.1 Press Release dated May 14, 2002

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

## CONNETICS CORPORATION

By: /s/ Katrina J. Church

Katrina J. Church Executive Vice President, Legal Affairs and General Counsel

Date: May 24, 2002

## EXHIBIT INDEX

Exhibit Number		Description	
99.1	Press Release dated May 14, 2002		

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# **CONNETICS CORP**

3400 W BAYSHORE RD PALO ALTO, CA 94303 415. 843.2800

**EX-99.1** 

EXHIBIT 99.1 8-K Filed on 05/24/2002 - Period: 05/14/2002 File Number 000-27406



EXHIBIT 99.1

Company Contact John L. Higgins Chief Financial Officer (650) 843-2800 jhiggins@connetics.com

Investor Relations Bruce Voss or Martin Halsall Lippert/Heilshorn & Associates (310) 691-7100 bvoss@lhai.com

Media Relations Kathy Vincent or Nurha Hindi Ruder Finn (310) 479-9929 vincentk@ruderfinn.com

### CONNETICS LICENSES VELAC(R) GEL FROM YAMANOUCHI

- -- FIRST IN CLASS ACNE PRODUCT TO TARGET \$1.6 BILLION UNITED STATES ACNE MARKET --
- -- CONFERENCE CALL TO BEGIN AT 11:00 A.M. EASTERN TIME TODAY--

PALO ALTO, CALIF. (MAY 14, 2002) -- Connetics Corporation (Nasdaq: CNCT), a specialty pharmaceutical company focused on the development and commercialization of dermatology products, today announced it has licensed Velac(R) gel (a first in class combination of 1% clindamycin, and 0.025% tretinoin) from Yamanouchi Europe B.V. Connetics has licensed exclusive rights to develop and commercialize the product in the U.S. and Canada, and has licensed non-exclusive rights in Mexico. Under the terms of the agreement, Connetics will pay Yamanouchi an initial \$2 million licensing fee, as well as future development milestones and royalties on product sales.

Connetics plans to request a pre-IND meeting with U.S. Food and Drug Administration (FDA) officials. Pending the outcome of the pre-IND meeting, current plans are to begin clinical trials early in 2003. Under the current development timeline, Connetics expects to file a New Drug Application (NDA) for Velac(R) gel with the FDA during the second half of 2004.

"The licensing of Velac(R) gel supports our corporate strategy of developing innovative therapies for use by dermatologists and their patients, and leveraging our impressive R&D, regulatory and sales force capabilities to the benefit of our shareholders. Velac(R) gel will compete in the prescription acne market, the largest segment of the dermatology market worth more than \$1.6 billion annually in the U.S., giving Velac(R) gel the potential to become our biggest selling product," said Thomas G. Wiggans, President and Chief Executive Officer of Connetics. "This is a tremendous opportunity for Connetics to expand our growing acne franchise and complement our foam formulation of clindamycin, which we expect to enter Phase III testing this summer."

"We are delighted to be partnering with Connetics," said Ian Talmage Vice President Strategic Marketing and Business Development at Yamanouchi Europe B.V. "As evidenced by their strong commitment to dermatology, we are pleased that they will lead the development and commercialization of Velac(R) gel in North America."

"This is a very exciting new combination product that brings together two leading drugs used to treat acne in one convenient formulation. Unlike currently available combination products, Velac(R) gel acts on multiple targets for treating acne," stated James Leyden, M.D., Professor of Dermatology, University of Pennsylvania Health System. "This combination will make it easier for patients to use, and will likely enhance their compliance."

### VELAC(R) GEL IN ACNE

In the U.S., an estimated 17 million people are affected by acne, of which an estimated 5.4 million visited a physician for treatment during the 12 months ended September 2001. Velac(R) gel is a novel, first in class, dual-active product combining the anti-inflammatory and antibiotic effects of clindamycin with the beneficial effects of tretinoin. These two single agents are among the most widely prescribed medications for acne: clindamycin (an anti-inflammatory antibiotic) and tretinoin (all-trans-retinoic acid). The product is patented in the U.S. and internationally.

"Acne is the most common skin disorder in the U.S., and is the leading category in the dermatology market representing more than 35 percent of dermatology product sales," said Greg Vontz, Chief Operating Officer of Connetics. "Given the robust clinical and manufacturing data that have been generated, as well as an intellectual property position, we believe Velac(R) gel has the potential to be one of the top acne products in North America."

Clinical trials in Europe have shown that Velac(R) gel is highly effective in treating acne. Results from clinical studies in more than 700 patients in Europe for the treatment of acne vulgaris have shown Velac(R) gel to be safe and as effective as leading topical treatments. Velac(R) gel is associated with few adverse events, limited mainly to mild skin irritations. In addition, Velac(R) gel is a novel formulation, for once daily application that spreads easily, dries quickly and does not stain.

### CONFERENCE CALL

Connetics will host a conference call today to discuss this announcement beginning at 11:00 a.m. Eastern Time (8:00 a.m. Pacific Time). To participate in the live call by telephone in the U.S., please call (888) 328-2575. To access the call from outside the U.S., please call (706) 643-0459, conference ID #4200609. The conference call will also be broadcast live over the Internet: follow the Investor Relations link at www.connetics.com.

A telephone replay will be available from 2:00 p.m. Eastern Time (11:00 a.m. Pacific Time) on May 14, 2002, to 3:00 a.m. Eastern Time (12:00 a.m. Pacific Time) on May 16, 2002. To access the replay from the U.S., please call (800) 642-1687. To access the replay from outside of the U.S., please call (706) 645-9291, conference ID #4200609. The call will also be available for replay on Connetics' web site for 60 days.

### ABOUT YAMANOUCHI

Yamanouchi Pharmaceutical Co., Ltd., is a worldwide organization committed to the research, development, manufacture and marketing of innovative pharmaceutical and healthcare products. Research is one of the company's core activities, and has resulted in a number of important innovations, including the H2 antagonist famotidine for the treatment of acid related disorders of the gastrointestinal tract, the calcium antagonist nicardipine for the treatment of high blood pressure and angina, and tamsulosin a treatment for the functional symptoms of benign prostatic hyperplasia. Yamanouchi was established in 1923, employs about 9,500 people worldwide and is headquartered in Tokyo, Japan. It is the third largest pharmaceutical company in Japan, and is expanding its business base in Europe, the United States and Asia. For more information about Yamanouchi, its operations and its products, please visit www.yamanouchi.com.

Yamanouchi Europe B.V. is a part of Yamanouchi Pharmaceutical Co., Ltd. and has its Headquarters and Research Laboratories in Leiderdorp, The Netherlands, and has subsidiaries in most European countries. Advanced production plants are located in Meppel (Netherlands) and Carugate (Italy). Its main therapeutic focus is in the area of urology and the company has significant business interests in the areas of dermatology and cardiology. In addition to its European operations, it exports to China, the Middle East, Latin America, Australia and New Zealand.

Velac(R) is a registered trademark of Yamanouchi Europe BV.

Contact:
Mr. G. Emmer,
Director Communications Europe
+31 71-545-5772

### ABOUT CONNETICS

Connetics Corporation is an independent pharmaceutical company focused on the development and commercialization of innovative therapeutics for the dermatology market. The Company's marketed products are Luxiq(R) (betamethasone valerate) Foam, 0.12% and OLUX(R) (clobetasol propionate) Foam, 0.05%. The Company's wholly owned subsidiary, Soltec Research Pty Ltd., is focused on discovering and developing innovative topical drug delivery formulations. These formulations aim to improve the management of dermatological diseases, provide significant product differentiation, and extend product life cycles. For more information about Connetics and its products, please visit Connetics' web site at www.connetics.com, or send an email to ir@connetics.com.

This news release contains forward-looking statements and predictions that represent the Company's judgment as of the date of this news release, and are subject to risks and uncertainties that could cause actual results or events to differ materially from those expressed in such forward-looking statements. Such statements are designated by language such as "we anticipate," "we expect," "we plan," and similar language. In particular, Connetics faces risks and uncertainties that U.S. development of Velac(R) may not succeed, that Velac(R) may not be approved for marketing in the U.S., that clinical trials of the product may not produce the same results as shown in earlier clinical trials, that physicians may not respond as favorably as anticipated to the product, that future sales of Velac(R) may not be as robust as anticipated,

that development of other product candidates in the Company's pipeline may not succeed, and that clinical trials may not go forward as planned. The actual results could differ materially from those contained in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, risks and other factors that are discussed in documents filed by Connetics with the Securities and Exchange Commission from time to time, including Connetics' most recently filed Annual Report on Form 10-K.

# # #

# EXHIBIT 9

# **CONNETICS CORP**

3400 W BAYSHORE RD PALO ALTO, CA 94303 415. 843.2800

# 8-K

FORM 8-K Filed on 01/27/2004 - Period: 01/27/2004 File Number 000-27406



# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# FORM 8-K

**CURRENT REPORT** 

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

January 27, 2004

(Date of earliest event reported)

# **CONNETICS CORPORATION**

(Exact name of Registrant as specified in its charter)

Delaware	0-27406	94-3173928
(State or Other Jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)
3290 West Bayshore Road, P	alo Alto, California 94303	
(Address of principal avacutive	offices, including zip code)	
(Address of principal executive		
(650) 843	2800	

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  - (c) Exhibits.
    - 99.1 Earnings Press Release dated January 27, 2004.
- Item 12. Results of Operations and Financial Condition.

On January 27, 2004, Connetics Corporation, a Delaware corporation, issued a press release announcing earnings for the quarter ended December 31, 2003. A copy of the earnings release is furnished as Exhibit 99.1 to this report.

# **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CONNETICS CORPORATION

By: /s/ John L. Higgins

John L. Higgins Executive Vice President, Finance and Corporate Development, and Chief Financial Officer

Date: January 27, 2004

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Exhibit Number	Description
99.1	Press Release dated January 27, 2004

# **CONNETICS CORP**

3400 W BAYSHORE RD PALO ALTO, CA 94303 415. 843.2800

EX-99.1

EXHIBIT 99.1 8-K Filed on 01/27/2004 - Period: 01/27/2004 File Number 000-27406



Exhibit 99.1

Company Contact John L. Higgins Chief Financial Officer (650) 843-2800 jhiggins@connetics.com

Investor Relations
Bruce Voss or Ina McGuinness
Lippert/Heilshorn & Associates
(310) 691-7100
bvoss@lhai.com

#### CONNETICS REPORTS FOURTH QUARTER EPS OF \$0.05 ON 41% INCREASE IN PRODUCT REVENUE

### Introduces 2004 full year and first quarter financial guidance

PALO ALTO, Calif. (January 27, 2004) — Connetics Corporation (Nasdaq NM: CNCT), a specialty pharmaceutical company focused on the development and commercialization of dermatology products, today reported product revenues for the fourth quarter of 2003 rose 41% to \$19.1 million, compared with \$13.6 million, for the comparable quarter last year. Fourth quarter total revenues (which include royalties and contract payments) rose 36% to \$20.3 million, from \$15.0 million for the fourth quarter of last year.

The Company reported net income for the 2003 fourth quarter of \$1.6 million, or \$0.05 per diluted share, compared with a net loss of \$5.6 million, or \$0.18 per share, for the 2002 fourth quarter, which includes a non-recurring in-process R&D cost of \$2.4 million.

"We are proud to report our second consecutive quarter of profitability, and continued strong gains in product sales and prescription growth for our two marketed products, OLUX and Luxíq," said Thomas G. Wiggans, Connetics President and Chief Executive Officer. "Connetics is now a profitable growth company with solid financial performance, significant progress in our product pipeline and a bright future. Looking back over 2003, we had a very successful year, yet just as important, these accomplishments built a solid foundation for continued growth and success," added Wiggans.

For the year ended December 31, 2003, product revenues rose 40% to \$66.6 million, compared with \$47.6 million in 2002. Total revenues for 2003 rose 43% to \$75.3 million, up from \$52.8 million in 2002. The 2003 net loss was \$4.0 million, or \$0.13 per share. The Company reported a net loss for 2002 of \$16.6 million, or \$0.54 per share, including non-recurring in-process R&D costs of \$4.4 million and a gain on sale of stock of \$2.1 million.

Total cash, cash equivalents and investments as of December 31, 2003 were \$115.0 million.

#### Fourth Quarter Highlights

During the 2003 fourth quarter and subsequent weeks, Connetics made substantial progress in all areas of its operations, including:

· Recording a quarter of strong product sales and the second consecutive quarter of profitability.

- Submitting a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for Actiza<sup>TM</sup>, an investigational new drug formulation of 1% clindamycin delivered in the Company's proprietary VersaFoam<sup>TM</sup> delivery system, as a potential new topical treatment for acne.
- Reaching a favorable conclusion that Connetics does not owe a User Fee for the Extina™ NDA, an investigational new drug formulation of 2% ketoconazole delivered in the VersaFoam delivery system, as a potential new treatment for seborrheic dermatitis.
- Completing enrollment in two Phase III clinical trials for Velac® Gel, a first-in-class combination of 1% clindamycin and 0.025% tretinoin, for the treatment of acne. The two Phase III trials included over 2,200 patients at 37 centers.

## 2004 Full Year and First Quarter Financial Guidance

The Company expects full—year 2004 product sales to be between \$86 million and \$92 million, and total revenues to be between \$88 million and \$96 million. Combined OLUX® and Luxiq® revenue for 2004 are projected to be \$82 million to \$86 million. Connetics projects combined SG&A and R&D expenses for 2004 to be between \$71 million to \$73 million. Net interest expense for 2004 is projected to be \$1.0 million to \$1.5 million. Diluted earnings per share (EPS) for 2004 are projected to be \$0.21 to \$0.25, based on an estimated 34.5 million diluted shares and an estimated effective tax rate of 12%.

The Company expects first quarter 2004 product sales to be between \$19.5 million and \$20.5 million, and total revenues to be between \$20.5 million and \$21.5 million. Connetics projects combined SG&A and R&D expenses for the first quarter to be between \$19 million and \$20 million. First quarter 2004 diluted EPS is projected to be \$0.01 to \$0.02, with tax rate comparable to the full-year guidance.

#### Conference Call

Connetics will host a conference call to discuss fourth quarter results and 2004 financial guidance today beginning at 4:30 p.m. Eastern Time (1:30 p.m. Pacific Time). To participate in the live call by telephone, domestic callers should dial (888) 328–2575, and international callers should dial (706) 643–0459. Those interested in listening to the conference call live via the Internet may do so by visiting the investor relations section of the Company's Web site at www.connetics.com.

A telephone replay will be available for 48 hours beginning January 27, 2004, at 6:30 p.m. Eastern Time (3:30 p.m. Pacific Time). To access the replay from the U.S., please call (800) 642–1687. To access the replay from outside of the U.S., please call (706) 645–9291. Enter the Conference ID# 5099844. The call will also be available for replay for 30 days on the Connetics Web site at www.connetics.com.

#### **About Connetics**

Connetics Corporation is a specialty pharmaceutical company focused on the development and commercialization of innovative therapeutics for the dermatology market. The Company's marketed products are OLUX® (clobetasol propionate) Foam, 0.05% and Luxíq® (betamethasone valerate)

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Foam, 0.12%. Connetics is also developing Extina<sup>TM</sup>, a foam formulation of the antifungal drug ketoconazole, Actiza<sup>TM</sup>, a foam formulation of clindamycin for treating acne, and Velac® Gel, a combination of clindamycin and tretinoin for treating acne. Connetics has branded its innovative foam drug delivery vehicle, VersaFoam<sup>TM</sup>. These formulations aim to improve the management of dermatological diseases and provide significant product differentiation. For more information about Connetics and its products, please visit www.connetics.com, or send an e-mail to ir@connetics.com.

#### Forward-Looking Statements

This news release includes forward—looking statements, and predictions, including statements about continued revenue growth, projected 2004 full year and first quarter product and total revenues and earnings projections, the market potential of certain products and product candidates, and the potential value of pipeline products. These statements represent the Company's judgment as of the date of this news release and are subject to risks and uncertainties that could cause actual results or events to differ materially from those expressed in such forward—looking statements. In particular, Connetics faces risks and uncertainties that it may not be able to sustain profitability, that revenues may be lower or expenses higher than projected, that product sales may not increase, that development of product candidates in the Company's pipeline may not succeed or that clinical trials may not go forward as planned, and that the FDA may not approve the NDAs for Extina or Actiza or that the markets for those products may not materialize. Factors that could cause or contribute to such differences include, but are not limited to, risks and other factors that are discussed in documents filed by Connetics with the Securities and Exchange Commission from time to time, including Connetics' Annual Report on Form 10–K/A–2 filed on December 2, 2003, and the Form 10–Q for the quarter ended September 30, 2003.

[Tables to Follow]

# CONNETICS CORPORATION Condensed Statements of Operations (In thousands, except per share amounts) (Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2003	2002	2003	2002
Revenues: Product Contract and royalty	\$19,115 1,223	\$13,561 1,404	\$66,606 8,725	\$ 47,573 5,190
Total revenues	20,338	14,965	75,331	52,763
Operating costs and expenses: Cost of product revenues Depreciation and amortization Research and development Selling, general and administrative In-process R&D Charge (credit) for relaxin program	1,484 574 6,518 9,994	1,425 545 8,023 8,387 2,350	5,129 2,241 29,560 40,791	4,190 2,085 25,330 36,030 4,350 312
Total operating expenses Interest and other income/(expense) Gain on sale of stock Income tax expense/(credit)	18,570 (254) — (124)	20,730 271 116	77,721 (426) 1,167	72,297 1,039 2,086 181
Net income/(loss)	\$ 1,638	\$ (5,610)	\$ (3,983)	\$(16,590)
Basic net income/(loss) per share	\$ 0.05	\$ (0.18)	\$ (0.13)	\$ (0.54)
Diluted net income/(loss) per share	\$ 0.05	\$ (0.18)	\$ (0.13)	\$ (0.54)
Shares used to calculate basic net income/(loss) per share	31,781	31,058	31,559	30,757
Shares used to calculate diluted net income/(loss) per share	33,754	31,058	31,559	30,757

# Condensed, Consolidated Balance Sheets (In thousands) (Unaudited)

	December 31, 2003	December 31, 2002
Assets	A CONTRACTOR	
Assets:  Cash and investments Accounts receivable and other current assets Property and equipment, net Long-term assets and other	\$114,966 7,408 5,628 17,895	\$33,788 6,111 5,860 13,794
Total assets	\$145,897	\$59,553
Liabilities and Stockholders' Equity Liabilities and stockholders' equity: Current liabilities Other liabilities Stockholders' equity	\$ 10,010 90,016 45,871	\$14,414 396 44,743
Total liabilities and stockholders' equity	\$145,897	\$59,553

# EXHIBIT 10

# **CONNETICS CORP**

3400 W BAYSHORE RD PALO ALTO, CA 94303 415. 843.2800

8-K

FORM 8-K Filed on 03/24/2004 - Period: 03/23/2004 File Number 000-27406



# **Table of Contents**

# SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

# FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

March 23, 2004

(Date of earliest event reported)

# **CONNETICS CORPORATION**

(Exact name of Registrant as specified in its charter)

Delaware

0-27406

94-3173928

(State or Other Jurisdiction of Incorporation)

(Commission File No.)

(IRS Employer Identification No.)

3290 West Bayshore Road, Palo Alto, California 94303 (Address of principal executive offices, including zip code)

(Registrant's telephone number, including area code)

1

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Item 5. Other Events.

On March 23, 2004, Connetics Corporation announced the positive outcome of its Phase III clinical trials evaluating Velac® in the topical treatment of acne vulgaris. Velac is a first-in-class, once-a-day treatment combination of 1% clindamycin and 0.025% tretinoin in an aqueous gel.

A copy of the press release announcing this event is attached to this Report as Exhibit 99.1 and is incorporated into this report by this reference.

Item 7. Financial Statements and Exhibits.

(c) Exhibits.

99.1 Press Release dated March 23, 2004.

## **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CONNETICS CORPORATION

By: /s/ Katrina J. Church

Katrina J. Church Executive Vice President, General Counsel and Secretary

Date: March 24, 2004

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Exhibit Number	Description
99.1	Press Release dated March 23, 2004

# **CONNETICS CORP**

3400 W BAYSHORE RD PALO ALTO, CA 94303 415. 843.2800

EX-99.1

**EXHIBIT 99.1 8–K Filed on 03/24/2004 – Period: 03/23/2004**File Number 000–27406



EXHIBIT 99.1

#### (CONNETICS LOGO)

COMPANY CONTACT

\_\_\_\_\_\_ John Higgins (650) 843-2800

jhiggins@connetics.com

INVESTOR RELATIONS

Ina McGuinness or Bruce Voss Chief Financial Officer Lippert/Heilshorn & Associates (310) 691-7100 imcguinness@lhai.com

MEDIA CONTACT

Danine Summers VP, Marketing (650) 843-2800 dsummers@connetics.com

## CONNETICS ANNOUNCES POSITIVE RESULTS FROM VELAC PHASE III PIVOTAL TRIALS

COMPANY EXPECTS TO SUBMIT NDA FOR FIRST-IN-CLASS TRIPLE-ACTION ACNE TREATMENT IN THIRD OUARTER

PALO ALTO, CALIF. (MARCH 23, 2004) - Connetics Corporation (Nasdaq: CNCT), a specialty pharmaceutical company focused on dermatology, today announced the positive outcome of its Phase III clinical trials evaluating Velac(R) in the topical treatment of acne vulgaris. Velac is a first-in-class, once-a-day treatment combination of 1% clindamycin and 0.025% tretinoin in an aqueous gel.

The two Velac Phase III trials comprise the largest-ever pivotal program conducted by Connetics and included more than 2,200 patients with mild-to-moderate acne at 37 centers, in which patients were treated for 12 weeks in double-blinded, placebo- and active-controlled studies. The Phase III trials were of identical design evaluating the beneficial effect of Velac compared with each of the single active ingredients, clindamycin gel and tretinoin gel, and with the placebo gel on two primary efficacy endpoints: Lesion Count and Investigator's Static Global Assessment (ISGA). The Lesion Count endpoint is measured as a percent reduction in two out of three lesion counts (inflammatory, non-inflammatory and total). Treatment success based on ISGA is measured as the proportion of patients who are clear or almost clear of lesions at the end of treatment.

The data from each trial demonstrated a consistently robust and statistically superior treatment effect for Velac compared with clindamycin gel, tretinoin gel and placebo gel on both of the primary endpoints. An analysis of the combined data from the two clinical trials demonstrated similar results to the individual trials. In the combined analysis, the proportion of patients achieving treatment success on the ISGA were: 37% Velac, 27% clindamycin gel, 25% tretinoin gel and 14% vehicle gel (p<0.0001 for all comparisons). The mean percent reduction in total lesion counts was: 49% Velac, 38% clindamycin gel, 40% tretinoin gel and 23% vehicle gel (p<0.0001 for all comparisons).

The data from these trials also demonstrated that Velac was safe and well tolerated, with the most commonly observed adverse effects being application site reactions (e.g. burning, dryness, redness and peeling).

"We are delighted with the strength of the Velac pivotal data, and look forward to the prospect of bringing this significant advancement in the treatment of acne to dermatologists and their patients.

As Velac is a patent-protected, first-in-class combination product, we expect it to play an important role as we build a strong franchise in the \$1 billion U.S. acne market. Acne is one of the largest segments in dermatology, and Velac, if approved, targets three of the four causes of acne and represents the largest sales potential of any product in our pipeline, "said Thomas G. Wiggans, President and Chief Executive Officer of Connetics.

"The Velac development program has consistently met or exceeded our expectations on timing and results. I express my sincere thanks to our Connetics team, the clinical investigators and their staffs, and the patients who participated in these trials. This team has done a fantastic job in planning and executing a premier development program," he added. "We look forward to submitting a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in the third quarter to seek approval to market Velac in the U.S."

Velac increases the opportunity for Connetics to take a leadership position in the acne market and complements Actiza(TM), an investigational new drug formulation of 1% clindamycin delivered in the Company's proprietary VersaFoam(TM) delivery system. The FDA has accepted the Actiza NDA for filing as of December 24, 2003.

"These trials have met the highest standards for regulatory approval by achieving statistical superiority on both lesion count and ISGA endpoints," said Lincoln Krochmal, M.D., Executive Vice President, Research & Product Development. "The overall clinical benefits achieved in patients treated with Velac were excellent, with more than one in three being clear or almost clear at 12 weeks having had lesion counts ranging from 35 to 200. The breakthrough formulation technology to stabilize the two active ingredients along with the significantly superior clinical results seen in the pivotal trials has the potential to result in a new paradigm in acne therapy."

"As a member of The Global Alliance for Better Outcomes in Acne, we have been advocating the use of topical retinoids in combination with topical antibiotics as the backbone of treatment for the vast majority of acne patients," said James Leyden, M.D., Professor of Medicine, University of Pennsylvania, and Principal Investigator in the Velac pivotal program. "Now, for the first time we have the two most commonly used agents in one vehicle to help deliver on this treatment approach."

# ABOUT VELAC

Velac is a once daily topical treatment that combines clindamycin, the No. 1 prescribed topical antibiotic for acne, and tretinoin, the No. 1 prescribed topical retinoid for acne. The combination drug has a triple-action effect combining the anti-inflammatory and antimicrobial effects of clindamycin with the beneficial comedolytic effects of tretinoin in normalizing the plugging of pores, which leads to acne lesions. Velac is delivered in an elegant, non-alcoholic gel. In May 2002, Connetics licensed rights from Yamanouchi Europe B.V. to develop and commercialize Velac exclusively in the U.S. and Canada, and non-exclusively in Mexico. Velac is approved in Europe.

### ABOUT CONNETICS

Connetics Corporation is a specialty pharmaceutical company focused on the development and commercialization of innovative therapeutics for the dermatology market. The Company's marketed products are OLUX(R) (clobetasol propionate) Foam, 0.05%, Luxiq(R) (betamethasone valerate) Foam, 0.12%, and Soriatane(R) (acitretin) capsules, 10 mg and 25 mg. Connetics is developing Extina(TM), a foam formulation of the antifungal drug ketoconazole, Actiza(TM), a foam formulation of clindamycin for treating acne, and Velac(R), a combination of clindamycin and tretinoin for treating acne. Connetics has branded its innovative foam drug delivery vehicle VersaFoam(TM). These formulations aim to improve the management of dermatological diseases and

provide significant product differentiation, and have earned wide acceptance by both physicians and patients due to their clinical effectiveness, high quality and cosmetic elegance. For more information about Connetics and its products, please visit www.connetics.com.

Except for historical information, this press release includes "forward-looking statements" within the meaning of the Securities Litigation Reform Act. All statements included in this press release that address activities, events or developments that Connetics expects, believes or anticipates will or may occur in the future are forward-looking statements, including specifically comments about the timing of filing an NDA, the market potential for Velac, and the likelihood of approval of Velac. These statements are based on certain assumptions made by Connetics' management based on experience and perception of historical trends, current conditions, expected future developments and other factors it believes are appropriate in the circumstances. Such statements are subject to a number of assumptions, risks and uncertainties, many of which are beyond Connetics' control, and which could cause actual results or events to differ materially from those expressed in such forward-looking statements. Any such projections or statements include Connetics' current views with respect to future events and financial performance. No assurances can be given, however, that these events will occur or that such results will be achieved. Factors that could cause or contribute to such differences include, but are not limited to, risks and other factors that are discussed in documents filed by Connetics with the Securities and Exchange Commission from time to time, including Connetics' Annual Report on Form 10-K filed on March 15, 2004. Forward-looking statements represent the judgment of the Company's management as of the date of this release, and Connetics' disclaims any intent or obligation to update any forward-looking statements.

NOTE: Full prescribing information for any Connetics prescription product is available by contacting the Company.

# # #

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# EXHIBIT 11

# **CONNETICS CORP**

3400 W BAYSHORE RD PALO ALTO, CA 94303 415. 843.2800

8-K

FORM 8-K Filed on 05/04/2004 - Period: 05/04/2004 File Number 000-27406



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# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

May 4, 2004

(Date of earliest event reported)

# **CONNETICS CORPORATION**

(Exact name of Registrant as specified in its charter)

Delaware

0-27406

94-3173928

(State or Other Jurisdiction of Incorporation)

(Commission File No.)

(IRS Employer Identification No.)

3290 West Bayshore Road, Palo Alto, California 94303

(Address of principal executive offices, including zip code)

(650) 843-2800

(Registrant's telephone number, including area code)

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## Item 7. Financial Statements and Exhibits.

(c) Exhibits.

99.1 Earnings Press Release dated May 4, 2004.

# Item 12. Results of Operations and Financial Condition.

On May 4, 2004, Connetics Corporation, a Delaware corporation, issued a press release announcing earnings for the quarter ended March 31, 2004. A copy of the earnings release is furnished as Exhibit 99.1 to this report.

# **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

## CONNETICS CORPORATION

By: /s/ John L. Higgins

John L. Higgins Executive Vice President, Finance and Corporate Development, and Chief Financial Officer

Date: May 4, 2004

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Exhibit Number	Description
99.1	Press Release dated May 4, 2004

# **CONNETICS CORP**

3400 W BAYSHORE RD PALO ALTO, CA 94303 415. 843.2800

EX-99.1

**EXHIBIT 99.1 8–K Filed on 05/04/2004 – Period: 05/04/2004**File Number 000–27406



EXHIBIT 99.1

Company Contact: John Higgins Chief Financial Officer (650) 843-2800 jhiggins@connetics.com

Investor Relations: Ina McGuinness or Bruce Voss Lippert/Heilshorn & Associates (310) 691-7100 imcguinness@lhai.com

CONNETICS REPORTS FIRST QUARTER EPS OF \$0.05, PRODUCT REVENUES INCREASE 65% TO \$23.6 MILLION

Company Raises 2004 Sales Guidance for All Three of its Products and Introduces Second Quarter Financial Guidance

PALO ALTO, Calif. (May 4, 2004) - Connetics Corporation (Nasdaq: CNCT), a specialty pharmaceutical company that develops and commercializes dermatology products, today reported net income for the first quarter ended March 31, 2004 of \$1.9 million, or \$0.05 per share on a fully diluted basis. This compares with a net loss for the 2003 first quarter of \$5.4 million, or \$0.17 per share.

Total revenues for the first quarter of 2004 increased 63% to \$25.0 million, compared with total revenues of \$15.3 million for the first quarter of 2003. Product revenues for the quarter were \$23.6 million, including \$19.8 million in sales of OLUX(R) and Luxiq(R), an increase of 39% over sales of \$14.3 million for those two products in the first quarter of 2003. In addition, the Company booked \$3.6 million in sales of Soriatane(R) during the first quarter of 2004. Connetics acquired exclusive U.S. rights to Soriatane(R)-brand acitretin from Hoffmann-La Roche, Inc. on March 4, 2004 and therefore there are no comparative 2003 sales figures. Contract and royalty revenues for the first quarter of 2004 were \$1.4 million, compared with \$1.0 million for the first quarter of 2003.

Selling, general and administrative costs increased to \$15.1 million in the first quarter of 2004, compared with \$10.7 million in the first quarter of 2003, due primarily to costs associated with an expanded sales force and Soriatane-related costs. Research and development expenses for the first quarter of 2004 were \$4.3 million, down from \$8.5 million in the first quarter 2003. The decrease in R&D expenses is primarily due to lower clinical trial expenses as a result of the completion of the Extina(R), Actiza(TM) and Velac(R) pivotal trials in 2003.

Effective with the first quarter of 2004, Connetics is including on the balance sheet certain manufacturing support and quality assurance costs as capitalized finished goods inventory and prepaid sample costs. These costs had previously been classified as R&D expense. These costs will be charged to the income statement either as cost of goods sold upon the sale of finished goods, or to SG&A expense upon the distribution of product samples. In the first quarter of 2004, \$763,000 in net income, or approximately \$0.02 per diluted share, is attributable to capitalizing these costs in inventory and prepaid samples. The Company has determined that the effect of accounting for these costs as inventory and prepaid samples would not have a material impact on its financial statements in any prior quarterly or annual period.

## FIRST QUARTER HIGHLIGHTS

Highlights of the 2004 first quarter and subsequent weeks include:

- o Announcing the positive outcome of Phase III clinical trials evaluating Velac, a first-in-class, once-daily combination treatment for acne;
- o Completing the acquisition of exclusive U.S. rights to Soriatane, a once-daily oral treatment for severe psoriasis in adults;
- o Entering a co-promotion agreement with UCB Pharma, Inc. to market OLUX and Luxiq to a select group of primary care physicians (PCPs). Connetics sales and marketing activities will continue to focus on dermatologists while UCB will be educating this group of PCPs on these two Connetics products;
- o Presenting 11 scientific posters at the American Academy of Dermatology's 62nd annual meeting;
- O Closing a 3.0 million share common stock private placement that generated gross proceeds of \$60.8 million to help fund the acquisition of Soriatane;
- o Receiving notice of acceptance by the U.S. Food and Drug Administration (FDA) of the Company's New Drug Application (NDA) for Actiza, a potential new topical treatment for acne in the VersaFoam(TM) delivery system. The FDA set the PDUFA date as October 26, 2004;
- o Receiving notice of acceptance by the FDA of the NDA filing for Extina, a potential new treatment for seborrheic dermatitis in the VersaFoam delivery system. The FDA set the PDUFA date as September 24, 2004.

"Our business operations so far this year encompass a broad range of accomplishments that we believe will continue our rapid growth and development," said Thomas Wiggans, President and CEO. "Based on our sales and marketing initiatives, coupled with our important new partnership with UCB, we project prescriptions for OLUX and Luxiq will continue to grow into 2005. With our acquisition of Soriatane, we now have a broad range of products for the treatment of all levels of psoriasis severity. We believe there is a real opportunity to expand the market for oral treatments for psoriasis by providing Soriatane information and support to dermatologists and their patients."

"Finally, with two NDAs filed and a projected third quarter NDA filing for Velac, we are in position to launch three new products within the next 18 months. We remain very optimistic about the prospects for continued growth of our current brands, and are actively undertaking preparations for the potential launch of new products," Wiggans continued.

INCREASED 2004 REVENUE AND EARNINGS GUIDANCE; SECOND QUARTER GUIDANCE

Based on Company expectations for continued prescription growth for its core products OLUX and Luxiq, as well as sales of Soriatane above expectations since the time of acquisition, Connetics raised 2004 financial guidance. Product revenues are now expected to be \$126 million to \$134 million, with sales of OLUX and Luxiq totaling \$87 million to \$91 million. This compares with prior guidance for product revenues of \$114 million to \$122 million, including \$82 million to \$86 million for OLUX and Luxiq. Total revenues (which include royalties and contract payments) are expected to be \$128 million to \$137 million.

Connetics projects total operating expenses for 2004 will be \$87.5 million to \$89.5 million, reflecting increased expenses associated with the co-promotional activities of UCB for OLUX and Luxiq, and additional marketing costs to support pre-launch activities for its products. Based on the successful outcome of Phase III trials for Velac, Connetics projects it will make a \$3.5 million milestone payment to Yamanouchi in the third quarter (concurrent with the projected submission of the Velac NDA). Diluted earnings per share for 2004 are projected to be \$0.33 to \$0.37, including new guidance of a \$0.10 per share charge in the third quarter for the \$3.5 million milestone payment to Yamanouchi.

For the second quarter 2004, the Company projects total revenue of \$31.5 million to \$34.0 million, including OLUX and Luxiq product revenues of \$21 million to \$22 million. Second quarter operating expenses are projected to be \$22.5 million to \$24.0 million. Diluted earnings per share for the second quarter are projected to be \$0.06 to \$0.08.

This guidance is based on information currently available to the Company.

#### CONFERENCE CALL

Connetics will host a conference call to discuss first quarter financial results and revised financial guidance today, beginning at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time. To participate in the live call by telephone, domestic callers should dial (888) 328-2575, and international callers should dial (706) 643-0459. To listen to the conference call live via the Internet, go to the investor relations section of www.connetics.com. A telephone replay will be available for 48 hours beginning today at 6:30 p.m. Eastern Time/3:30 p.m. Pacific Time. To access the replay from the U.S., please dial (800) 642-1687; and from outside the U.S. please dial (706) 645-9291. Enter the Conference ID# 6756090. The Internet replay of the call will be available for 30 days at www.connetics.com.

#### ABOUT CONNETICS

Connetics Corporation is a specialty pharmaceutical company focused on the development and commercialization of innovative therapeutics for the dermatology market. The Company's marketed products are OLUX(R) (clobetasol propionate) Foam, 0.05%, Luxiq(R) (betamethasone valerate) Foam, 0.12%, and Soriatane(R) (acitretin) capsules, 10 mg and 25 mg. Connetics is developing Extina(R), a foam formulation of the antifungal drug ketoconazole, Actiza(TM), a foam formulation of clindamycin for treating acne, and Velac(R), a combination of clindamycin and tretinoin for treating acne. Connetics has branded its innovative foam drug delivery vehicle VersaFoam(TM). These formulations aim to improve the management of dermatological diseases and provide significant product differentiation, and have earned wide acceptance by both physicians and patients due to their clinical effectiveness, high quality and cosmetic elegance. For more information about Connetics and its products, please visit www.connetics.com.

#### SAFE HARBOR STATEMENT

Except for historical information, this press release includes "forward-looking statements" within the meaning of the Securities Litigation Reform Act. All statements included in this press release that address activities, events or developments that Connetics expects, believes or anticipates will or may occur in the future are forward-looking statements, including statements about projected earnings, the revenue and earnings potential for the Company's products, and the timing of milestone payments and future FDA approvals, if any. These statements are based on certain assumptions made by Connetics' management based on experience and perception of historical trends, current conditions, expected future developments and other factors it believes are

appropriate in the circumstances. Such statements are subject to a number of assumptions, risks and uncertainties, many of which are beyond Connetics' control, and which could cause actual results or events to differ materially from those expressed in such forward-looking statements. Any such projections or statements include Connetics' current views with respect to future events and financial performance, and results of operations may fluctuate from period to period. No assurances can be given, however, that these events will occur or that such results will be achieved. In particular, Connetics faces risks and uncertainties that one or more of its product candidates Extina, Actiza and Velac may not be approved by the FDA in the timeframes projected, if at all; that Soriatane and the Company's other products may not produce the projected revenues and earnings; that sales may decline if generic or branded competitors enter the market; and that initial marketing success for Soriatane may or may not be achieved or may not be sustainable. Factors that could cause or contribute to such differences include, but are not limited to, risks and other factors that are discussed in documents filed by Connetics with the Securities and Exchange Commission from time to time, including Connetics' Annual Report on Form 10-K filed on March 15, 2004. Forward-looking statements represent the judgment of the Company's management as of the date of this release, and Connetics' disclaims any intent or obligation to update any forward-looking statements.

NOTE: Full prescribing information for any Connetics prescription product is available by contacting the Company.

# CONNETICS CORPORATION Condensed Consolidated Statements of Operations (In thousands, except per share amounts) (unaudited)

		THREE MONTHS ENDED MARCH 31,	
	2004	2003	
Revenues: Product Contract and royalty	\$ 23,566 1,416	\$ 14,311 1,000	
Total revenues	24,982	15,311	
Operating costs and expenses:  Cost of product revenues  Selling, general and administrative  Research and development  Depreciation and amortization	1,568 15,072 4,286 1,648	1,072 10,682 8,451 588	
Total operating costs and expenses	22,574	20,793	
Net interest and other income/(expense) Income tax benefit (expense)	(292) (243)	178 (77)	
Net earnings/(loss)	\$ 1,873	\$ (5,381)	
BASIC EARNINGS PER SHARE			
Net earnings/(loss) per basic share	\$ 0.06 =====	\$ (0.17) ======	
Shares used to calculate basic net earnings (loss) per share	33,587	31,286	
DILUTED EARNINGS PER SHARE Net earnings/(loss) per diluted share	\$ 0.05 ======		
Shares used to calculate diluted net earnings (loss) per share	35,887		

# CONDENSED CONSOLIDATED BALANCE SHEETS (In thousands) (unaudited)

# ASSETS

Assets:		
Cash, cash equivalents and short-term investments	\$ 44,143	\$114,966
Accounts receivables and other current assets	18,453	7,408
Soriatane asset, net	126,559	
Property and equipment, net	5,608	5,628
Other long-term assets	17,512	17,895
· ·		
Total assets	\$212,275	\$145,897
	=======	=======
LIABILITIES AND STOCKHOLDERS' EQUI	TY	
Liabilities and stockholders'equity:		
Current liabilities	\$ 16,869	\$ 10,127
Other liabilities	90,016	90,016
Stockholders' equity	105,390	45,754
Total liabilities and stockholders' equity	\$212,275	\$145,897
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# EXHIBIT 12

# **CONNETICS CORP**

3400 W BAYSHORE RD PALO ALTO, CA 94303 415. 843.2800

8-K

FORM 8-K Filed on 10/25/2004 - Period: 10/25/2004 File Number 000-27406



# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION **WASHINGTON, D.C. 20549**

# FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

October 25, 2004 Date of Report (Date of earliest event reported)

# **CONNETICS CORPORATION**

(Exact name of Registrant as specified in its charter)

	Delaware	0-27406	94–3173928	
	(State or Other Jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)	
		st Bayshore Road, Palo Alto, California of principal executive offices, including z		
	(Regis	(650) 843–2800 trant's telephone number, including area o	code)	
Check the appropriate following provision	iate box below if the Form 8-K filing is ns (see General Instruction A.2. below):	intended to simultaneously satisfy the fili	ing obligation of the registrant under any	of the
□ Written comm	unications pursuant to Rule 425 under the	ne Securities Act (17 CFR 230.425)		
☐ Soliciting mate	erial pursuant to Rule 14a-12 under the	Exchange Act (17 CFR 240.14a-12)		
☐ Pre-commenc	ement communications pursuant to Rule	: 14d-2(b) under the Exchange Act (17 Cl	FR 240.14d-2(b))	
□ Pre_commenc	ement communications pursuant to Rule	: 13e-4(c) under the Exchange Act (17 CI	FR 240.13e4(c))	

Filed 05/02/2008 Case 3:07-cv-02940-SI Document 105-3 Page 71 of 92 Item 2.02. Results of Operations and Financial Condition.
Item 9.01. Financial Statements and Exhibits.
SIGNATURES
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EXHIBIT 99.1

# **Table of Contents**

## Item 2.02. Results of Operations and Financial Condition.

On October 25, 2004 Connetics Corporation, issued a press release announcing earnings for the quarter ended September 30, 2004. A copy of the earnings release is furnished as Exhibit 99.1 to this report.

# Item 9.01. Financial Statements and Exhibits.

(c) Exhibits.

Exhibit Number	Description
99.1	Press Release dated October 25, 2004.

# **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

# CONNETICS CORPORATION

By: /s/ John L. Higgins

John L. Higgins Executive Vice President, Finance and Corporate Development, and Chief Financial Officer

Date: October 25, 2004

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## EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated October 25, 2004.

## **CONNETICS CORP**

3400 W BAYSHORE RD PALO ALTO, CA 94303 415. 843.2800

EX-99.1

**EXHIBIT 99.1 8–K Filed on 10/25/2004 – Period: 10/25/2004**File Number 000–27406





#### CONNETICS REPORTS THIRD QUARTER EARNINGS PER SHARE OF \$0.10

#### **Company Introduces 2004 Fourth Quarter Financial Guidance**

PALO ALTO, Calif. (October 25, 2004) — Connetics Corporation (Nasdaq: CNCT), a specialty pharmaceutical company that develops and commercializes dermatology products, today reported net income for the third quarter ended September 30, 2004 of \$3.7 million, or \$0.10 per diluted share, which includes a \$3.5 million milestone payment due to Yamanouchi Europe B.V. in conjunction with the submission of the Velac® New Drug Application (NDA). This compares with net income of \$1.6 million, or \$0.05 per diluted share, for the third quarter of 2003.

Total revenues for the third quarter of 2004 were \$37.3 million, compared with total revenues of \$19.7 million for the third quarter of 2003. Product revenues for the 2004 third quarter more than doubled to \$37.0 million, compared with \$17.7 million for the comparable period last year, reflecting growth in revenues of OLUX® and Luxíq®, and the addition of Soriatane®, which the Company acquired from Roche in March 2004. The Company had cash, cash equivalents and short-term investments on September 30, 2004 of \$78.0 million.

During the third quarter of 2004 revenues of OLUX and Luxíq were \$22.2 million, representing an increase of 26% over the prior year. Soriatane revenues were \$14.7 million during the third quarter of 2004. Contract and royalty revenues for the third quarter of 2004 were \$345,000, compared with \$2.1 million in the third quarter of 2003.

Selling, general and administrative (SG&A) expenses increased to \$16.8 million in the third quarter of 2004 from \$9.7 million in the third quarter of 2003. primarily due to payments made to UCB Pharma (UCB) for promotional activities on behalf of OLUX and Luxíq, increased promotional activities for all products and increased headcount. Research and development (R&D) expenses were \$6.0 million, essentially unchanged from the third quarter of 2003.

"I am delighted to report on our progress, particularly our recent regulatory milestones including the FDA approval of Evoclin™ and the filing of the NDA for our Velac product," said Thomas G. Wiggans, President and Chief Executive Officer of Connetics. "With the planned commercial launch of Evoclin in the fourth quarter, we continue to expand our commercial product portfolio and achieve our corporate goals and objectives. During October, we expanded our team of sales representatives to 124 from 66. Our new sales representatives are currently undergoing comprehensive training, and we look forward to their contribution beginning later this quarter. The Company continues to execute well on all fronts, and we are anticipating a strong finish to 2004."

Significant activities in the third quarter of 2004 and subsequent weeks included:

- Receiving FDA approval of Evoclin (clindamycin) Foam, 1% (formerly Actiza<sup>TM</sup>) for the topical treatment of mild-to-moderate acne vulgaris (October 2004). Evoclin is the first product approval for Connetics that will address the acne market. Evoclin is delivered in Connetics' proprietary VersaFoam® vehicle and will be available in the fourth quarter of 2004 in 50g and 100g sizes.
- The FDA's acceptance of the NDA filing for Velac, a once-a-day treatment combination of 1% clindamycin and 0.025% tretinoin in an aqueous gel for the topical treatment of acne vulgaris (October 2004).

- Signing a distribution agreement with a U.S.-based distributor that exports Soriatane to select international markets. Connetics built upon this
  relationship to include distribution of OLUX and Luxíq through this channel.
- Signing a license agreement granting Pierre Fabre Dermatologie exclusive commercial rights to OLUX for Europe excluding Italy, as well as marketing
  rights for certain countries in South America and Africa.
- Commencing a Phase III clinical trial with Desilux<sup>TM</sup>, a low-potency topical steroid formulated with 0.05% desonide in the Company's proprietary
  VersaFoam-EF<sup>TM</sup> (emollient formulation) delivery vehicle. The clinical trial program will focus on atopic dermatitis and is designed to address patients
  up to 17 years old. Subject to a successful Phase III trial outcome, Connetics anticipates submitting a New Drug Application to the FDA by the end of
  2005.
- Announcing the discontinuation of the UCB co-promotion agreement for OLUX and Luxíq to select primary care physicians effective March 31, 2005.
- Receiving FDA approval of a new 150g unit size for Luxíq which will help address the needs of chronic dermatoses patients and we anticipate will add growth to the brand in 2005.

#### Year-to-Date Financial Results

For the nine months ended September 30, 2004 net income was \$13.0 million, or \$0.35 per diluted share, which includes a third quarter \$3.5 million milestone payment to Yamanouchi associated with the filing of the Velac NDA. This compares with a net loss of \$5.6 million, or \$0.18 per share, for the comparable period last year.

Total revenues for the first nine months of 2004 rose to \$100.6 million, compared with \$55.0 million last year. Product revenues for the nine months ended September 30, 2004 more than doubled to \$98.6 million from \$47.5 million for the comparable period last year, reflecting growth in OLUX and Luxíq as well as two full quarters with revenues of Soriatane.

SG&A expenses increased to \$49.1 million for the first nine months of 2004 compared with \$30.8 million in the first nine months of 2003, primarily due to payments made to UCB for promotional activities related to OLUX and Luxíq, increased promotional activities for all products and increased headcount. R&D expenses for 2004 year—to—date were \$15.3 million, down from \$23.0 million during the same period last year as pivotal trials with Extina®, Evoclin and Velac were completed in 2003.

#### **Financial Guidance**

For the fourth quarter of 2004, Connetics projects product revenues of \$43.0 million to \$46.0 million. Fourth quarter combined SG&A and R&D expenses are projected to be in the range of \$27.0 million to \$31.0 million. Earnings per diluted share for the fourth quarter of 2004 are projected to be \$0.16 to \$0.18. As a result, full—year 2004 product revenues are expected to be \$142.0 million to \$145.0 million, compared with prior guidance of \$138.0 million to \$146.0 million. Earnings per diluted share for 2004 are expected to be \$0.51 to \$0.53, compared with prior guidance of \$0.48 to \$0.52.

In assessing the Company's financial guidance, Connetics' management considered many factors and assumptions including, but not limited to, current and projected prescription information; sales trend data of the Company's products; the potential generic availability of, and competitive threats to, the Company's products; size, reach and call frequency of the Company's selling organization; status, timing and progression of the Company's development projects; current and projected spending levels to support sales, marketing, development, and administrative activities; and other risk factors discussed in Connetics' publicly filed documents. The above guidance does not take into account conversion of the Company's convertible senior notes, the effect of expensing stock options or the potential impact of other components of Connetics' growth strategy, including possible future acquisitions of products, businesses and/or technologies.

#### Conference Call

Connetics will host a conference call to discuss third quarter financial results beginning at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time today. To participate in the live call by telephone, domestic callers should dial (888) 328–2575, and international callers should dial (706) 643–0459. To listen to the conference call live via the Internet, go to the investor relations section of www.connetics.com. A telephone replay will be available for 48 hours beginning today at 6:30 p.m. Eastern Time/3:30 p.m. Pacific Time. To access the replay from the U.S., please dial (800) 642–1687; and from outside the U.S. please dial (706) 645–9291. The Conference ID# is 1494516. The Internet replay of the call will be available for 30 days at www.connetics.com.

#### **About Connetics**

Connetics Corporation is a specialty pharmaceutical company focused on the development and commercialization of innovative therapeutics for the dermatology market. Connetics has branded its proprietary foam drug delivery vehicle VersaFoam®. The Company's marketed products are OLUX® (clobetasol propionate) Foam, 0.05%, Luxíq® (betamethasone valerate) Foam, 0.12%, and Soriatane® (acitretin) capsules. In October 2004, Connetics received approval for Evoclin<sup>TM</sup> (clindamycin) Foam, 1%. Connetics is developing Extina®, a foam formulation of the antifungal drug ketoconazole, and Velac®, a combination of clindamycin and tretinoin for treating acne. Our product formulations aim to improve the management of dermatological diseases and provide significant product differentiation, and in our marketed products have earned wide acceptance by both physicians and patients due to their clinical effectiveness, high quality and cosmetic elegance. For more information about Connetics and its products, please visit www.connetics.com.

#### **Forward Looking Statements**

Except for historical information, this press release includes "forward-looking statements" within the meaning of the Securities Litigation Reform Act. All statements included in this press release that address activities, events or developments that Connetics expects, believes or anticipates will or may occur in the future, including particularly statements about earnings estimates, future financial performance, and financial guidance, are forward-looking statements. Statements pertaining to revenue expectations, revenue growth, the timing and success of the launch of Evoclin, and the performance of Connetics' products or product candidates are also forward-looking statements. These forward-looking statements are based on certain assumptions made by Connetics' management based on experience and perception of historical trends, current conditions, expected future developments and other factors it believes are appropriate in the circumstances. Such statements are subject to a number of assumptions, risks and uncertainties, many of which are beyond Connetics' control, and which could cause actual results or events to differ materially from those expressed in such forward-looking statements. No assurances can be given that these events will occur or that such results will be achieved. Factors that could cause or contribute to such differences include, but are not limited to, risks and other factors that are discussed in documents filed by Connetics with the Securities and Exchange Commission from time to time, including Connetics' Annual Report on Form 10–K for the year ended December 31, 2003 and Form 10–Q for the quarter ended June 30, 2004. Forward-looking statements represent the judgment of the Company's management as of the date of this release, and Connetics disclaims any intent or obligation to update any forward-looking statements.

Contacts: Patrick O'Brien Director, Investor Relations (650) 739–2950 pobrien@connetics.com Ina McGuinness or Bruce Voss Lippert/Heilshorn & Associates (310) 691–7100 imcguinness@lhai.com

Tables Follow

## CONNETICS CORPORATION

Condensed Consolidated Statements of Operations (In thousands, except share and per share amounts) (Unaudited)

	Three Months Ended September 30,		Nine Mont Septem	
	2004	2003	2004	2003
Revenues: Product Royalty and contract	\$36,999 	\$17,652 2,060	\$ 98,564 2,015	\$47,491 7,502
Total revenues Operating costs and expenses: Cost of product revenues Research and development Selling, general and administrative Depreciation and amortization Acquired in–process research and development	37,344 3,067 6,038 16,789 3,738 3,500	19,712 1,388 6,021 9,729 624	100,579  8,213 15;281 49,100 9,153 3,500	54,993 3,645 23,042 30,797 1;667
Total operating costs and expenses Income / (loss) from operations Interest and other income (expense), net Provision for income taxes	33,132 4,212 (373) (144)	17,762 1,950 (321) (13)	85,247 15,332 (1,273) (1,034)	59,151 (4,158) (172) (1,291)
Net income / (loss)	\$ 3,695	\$ 1,616	\$ 13,025	\$(5,621)
Net income / (loss) per share: Basic	\$_0:10	\$ 0.05	\$ 0.37	\$ (0.18)
Diluted	\$ 0.10	\$ 0.05	\$ 0.35	\$ (0.18)
Shares used to calculate net income / (loss) per share: Basic	35,510	31,648	34,794	31,485
Diluted and the second	38,064	33,607	37,179	31,485

## CONNETICS CORPORATION

### Condensed Consolidated Balance Sheets (In thousands) (Unaudited)

	September 30, 2004	December 31, 2003
Assets Assets: Cash, cash equivalents and short-term investments Accounts receivable and other current assets Soriatane asset, net Property and equipment, net Other long-term assets	\$ 77,986 13,724 120,205	\$114,966 7,408
Total assets	\$239,726	\$145,897
Liabilities and Stockholders' Equity Liabilities and stockholders' equity: Current liabilities Other liabilities Stockholders' equity	\$ 30,006	
Total liabilities and stockholders' equity	\$239,726	\$ <u>145,897</u>

###

# EXHIBIT 13

# **CONNETICS CORP**

3400 W BAYSHORE RD PALO ALTO, CA 94303 415. 843.2800

8-K

FORM 8-K Filed on 01/25/2005 - Period: 01/25/2005 File Number 000-27406



## **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

## FORM 8-K

**CURRENT REPORT** 

Pursuant to Section 13 or 15(d) of the **Securities Exchange Act of 1934** 

<u>January 25, 2005</u>
Date of Report (Date of earliest event reported)

## CONNETICS CORPORATION

(Exact name of Registrant as specified in its charter)

Delaware

0-27406

94-3173928

(State or Other Jurisdiction of Incorporation)

(Commission File No.)

(IRS Employer Identification No.)

3290 West Bayshore Road, Palo Alto, California 94303 (Address of principal executive offices, including zip code)

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

Witten communications pursuant to Rule 423 under the Securities Act (17 CFR 230.423)	
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12) ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)) ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))	

Filed 05/02/2008 Page 83 of 92 Case 3:07-cv-02940-SI Document 105-3

Item 2.02. Results of Operations and Financial Condition.
Item 9.01. Financial Statements and Exhibits.
SIGNATURES
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EXHIBIT 99.1

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## **Table of Contents**

Item 2.02. Results of Operations and Financial Condition.

On January 25, 2005 Connetics Corporation, issued a press release announcing earnings for the quarter ended December 31, 2004. A copy of the earnings release is furnished as Exhibit 99.1 to this report.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits.

Exhibit No. Description

99.1 Press Release dated January 25, 2005.

## **Table of Contents**

## **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CONNETICS CORPORATION

By: /s/ John L. Higgins

John L. Higgins Executive Vice President, Finance and Corporate Development, and Chief Financial Officer

Date: January 25, 2005

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EXHIBIT INDEX

Exhibit <u>Number</u> Description

99.1 Press Release dated January 25, 2005

## **CONNETICS CORP**

3400 W BAYSHORE RD PALO ALTO, CA 94303 415. 843.2800

EX-99.1

**EXHIBIT 99.1 8–K Filed on 01/25/2005** – **Period: 01/25/2005**File Number 000–27406



EXHIBIT 99.1

#### [CONNETICS LOGO]

CONNETICS REPORTS FOURTH QUARTER EPS OF \$0.17 AND PRODUCT REVENUES UP 128% TO \$43.5 MILLION

CONCLUDES FIRST YEAR OF PROFITABILITY WITH \$0.52 EPS

PROVIDES FULL YEAR AND FIRST QUARTER 2005 FINANCIAL GUIDANCE

PALO ALTO, CALIF. (JANUARY 25, 2005) - Connetics Corporation (Nasdaq: CNCT), a specialty pharmaceutical company that develops and commercializes dermatology products, today reported record net income for the 2004 fourth quarter of \$6.4 million, or \$0.17 per diluted share, compared with \$1.5 million, or \$0.05 per diluted share, for the comparable quarter last year.

Total revenues for the fourth quarter of 2004 rose 115% to \$43.8 million, compared with \$20.3 million for the fourth quarter of 2003. Product revenues rose 128% to \$43.5 million, reflecting \$22.6 million in sales of OLUX(R) and Luxiq(R), \$18.0 million in sales of Soriatane(R) and \$2.9 million in sales of Evoclin(TM), which was launched in December 2004. Combined OLUX and Luxiq revenues increased 19% compared with the fourth quarter of 2003.

Selling, general and administrative (SG&A) expenses increased to \$22.8 million in the fourth quarter of 2004 from \$10.1 million in the fourth quarter of 2003, primarily due to payments made to UCB Pharma (UCB) for promotional activities on behalf of OLUX and Luxiq, launch-related costs for Evoclin, increased promotional activities for all products and increased headcount primarily related to Connetics' salesforce expansion. Research and development (R&D) expenses were \$5.7 million, down from \$6.5 million in the fourth quarter of 2003.

"Strong product revenue growth during 2004 contributed to our first full year of profitability and the fifth consecutive year of growth in our core brands OLUX and Luxiq," said Thomas G. Wiggans, President and Chief Executive Officer of Connetics. "Our first product in the acne market, Evoclin, was approved and launched during the fourth quarter. While early in the launch phase, the prescription data has been strong and the feedback from physicians has been encouraging, which we believe bodes well for a dynamic and expanding presence for Connetics in the acne market. We also marked the success of 2004 with the acquisition of Soriatane. Through our promotional efforts Soriatane was a significant financial contributor in 2004 and also was an important product for patients. With four marketed brands, a substantially expanded commercial team and a robust product pipeline, we believe Connetics is poised for another exciting and highly productive year."

Significant activities in the fourth quarter of 2004 and subsequent weeks included:

- 0 Receiving U.S. Food and Drug Administration (FDA) approval of Evoclin (clindamycin Foam, 1%) for the topical treatment of mild-to-moderate acne vulgaris, and the commencement of shipments to pharmaceutical wholesalers, retail pharmacies, hospitals and other institutional customers nationwide.
- Launching a comprehensive sales and marketing program for Evoclin that is expected to include a strong presence at relevant medical conferences, particularly in the first quarter of 2005, by way of poster and symposia presentations, as well as journal advertising, direct promotion, media relations and internet marketing campaigns.

- o Hiring 66 sales professionals, which more than doubled the salesforce to 124 professionals and positions Connetics as a strong commercial force in the dermatology market.
- o Receiving an FDA non-approvable letter for the Company's product candidate Extina(R). The Company plans to meet with the FDA early in 2005 to discuss the actions required to obtain approval for Extina.

#### 2004 FULL YEAR FINANCIAL RESULTS

Net income for 2004 was \$19.4 million, or \$0.52 per diluted share, which includes a third quarter \$3.5 million milestone payment to Yamanouchi associated with the filing of the Velac(R) New Drug Application. This compares with a net loss of \$4.1 million, or \$0.13 per share, for 2003.

Total revenues for 2004 rose 92% to \$144.4 million, and product revenues increased 113% to \$142.1 million, reflecting growth in OLUX and Luxiq, the addition of Soriatane in March and the launch of Evoclin in December.

SG&A expenses increased to \$71.9 million for 2004, compared with \$40.9 million for 2003, primarily due to payments made to UCB for promotional activities related to OLUX and Luxiq, increased promotional activities for all products and increased headcount. R&D expenses for 2004 were \$21.0 million, down from \$29.6 million during 2003 primarily due to the completion of pivotal trials with Extina, Evoclin and Velac.

Cash and investments, including restricted cash, totaled \$76.3 million on December 31, 2004.

2005 FULL YEAR AND FIRST QUARTER FINANCIAL GUIDANCE Connetics expects 2005 total revenues to be between \$190 million and \$200 million, representing an increase of 32% to 39% compared with 2004. Combined SG&A and R&D expenses are projected to be between \$116 million and \$123 million. Diluted EPS for 2005 is projected to grow by approximately 70% and to be in the range of \$0.88 to \$0.92, based on an estimated 42.3 million shares outstanding and an estimated effective tax rate of 10%. Assuming FDA approval of Velac during 2005, the Company anticipates making a milestone payment of \$5 million to Yamanouchi. This payment will be capitalized and amortized over the life of the patent, which expires in 2014.

The Company expects first quarter 2005 total revenues to be between \$42 million and \$44 million. Consistent with prior years of heavier expenditures in the first quarter compared with the immediately preceding quarter, Connetics projects combined SG&A and R&D expenses for the first quarter to range from \$33.5 million to \$35.5 million, reflecting a significant presence at dermatology conferences during the quarter, an increase in product promotion costs, particularly the Evoclin launch, and higher costs associated with a significantly expanded salesforce. Connetics projects net income per share for the first quarter of 2005 of \$0.01 or \$0.02.

In assessing the Company's financial guidance, Connetics' management considered many factors and assumptions including, but not limited to, current and projected prescription information; sales trend data; the potential generic availability of, and competitive threats to, the Company's products; size, reach and call frequency of the Company's selling organization; status, timing and progression of the Company's development projects; current and projected spending levels to support sales, marketing, development and administrative activities; and other risk factors discussed in Connetics' publicly filed documents. The above guidance does not take into account the effect of expensing stock options.

## CONFERENCE CALL

Connetics management will host a conference call to discuss the Company's financial performance today at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time. To participate in the live call, domestic callers should dial (888) 328-2575, international callers should dial (706) 643-0459 or the web cast can be accessed from the investor relations section of the Company's website at www.connetics.com. A telephone replay can be accessed for 48 hours beginning today at 6:30 p.m. Eastern Time/3:30 p.m. Pacific Time from the U.S., by

dialing (800) 642-1687, or (706) 645-9291 from outside the U.S. The Conference ID# is 3252801. The internet replay of the call will be available for 30 days at www.connetics.com.

#### ABOUT CONNETICS

Connetics Corporation is a specialty pharmaceutical company focused on the development and commercialization of innovative therapeutics for the dermatology market. Connetics has branded its proprietary foam drug delivery vehicle VersaFoam(R). The Company's marketed products are OLUX(R) (clobetasol propionate) Foam, 0.05%, Luxiq(R) (betamethasone valerate) Foam, 0.12%, Soriatane(R) (acitretin) capsules and Evoclin(TM) (clindamycin) Foam, 1%. Connetics is developing Velac(R) (a combination of 1% clindamycin and 0.025% tretinoin) Gel, for treating acne, and Desilux(TM) (desonide) VersaFoam-EF, 0.05% a low-potency topical steroid formulated to treat atopic dermatitis. Connetics' product formulations aim to improve the management of dermatological diseases and provide significant product differentiation. In the Company's marketed products, these formulations have earned wide acceptance by both physicians and patients due to their clinical effectiveness, high quality and cosmetic elegance. For more information about Connetics and its products, please visit www.connetics.com.

#### FORWARD LOOKING STATEMENTS

Except for historical information, this press release includes "forward-looking statements" within the meaning of the Securities Litigation Reform Act. All statements included in this press release that address activities, events or developments that Connetics expects, believes or anticipates will or may occur in the future, including particularly statements about earnings estimates, future financial performance and financial guidance, are forward-looking statements. Statements pertaining to revenue expectations, revenue growth, the timing and success of the launch of Evoclin and performance of other of Connetics' products or product candidates are also forward-looking statements. These forward-looking statements are based on certain assumptions made by Connetics' management based on experience and perception of historical trends, current conditions, expected future developments and other factors it believes are appropriate in the circumstances. Such statements are subject to a number of assumptions, risks and uncertainties, many of which are beyond Connetics' control, and which could cause actual results or events to differ materially from those expressed in such forward-looking statements. No assurances can be given that these events will occur or that such results will be achieved. Factors that could cause or contribute to differences in actual results or events include, but are not limited to, risks and other factors that are discussed in documents filed by Connetics with the Securities and Exchange Commission from time to time, including Connetics' Annual Report on Form 10-K for the year ended December 31, 2003 and Form 10-Q for the quarter ended September 30, 2004. Connetics disclaims any intent or obligation to update any forward-looking statements, which represent the judgment of the Company's management as of the date of this release.

## CONTACTS:

Patrick O'Brien Director, Investor Relations (650) 739-2950 pobrien@connetics.com Press Release Code: CNCT-F

Ina McGuinness or Bruce Voss Lippert/Heilshorn & Associates (310) 691-7100 imcguinness@lhai.com

# CONNETICS CORPORATION CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS) (UNAUDITED)

	THREE MONTHS ENDED DECEMBER 31,		TWELVE MONTHS ENDED DECEMBER 31,	
	2004	2003	2004	2003
Revenues: Product Royalty and contract	\$ 43,495 281	\$ 19,115 1,223	\$ 142,059 2,296	\$ 66,606 8,725
Total revenues	\$ 43,776		144,355	75,331
Operating costs and expenses:    Cost of product revenues    Research and development    Selling, general and administrative    Depreciation and amortization    Acquired in-process research and development and    milestone payments	22,849 3,750	1,484 6,518 10,111 574	71,949 12,903 3,500	5,129 29,561 40,908 2,240
Total operating costs and expenses	36,729	18,687	121,976	77,838
Income (loss) from operations	7,047	1,651	22,379	(2,507)
Interest and other income (expense), net	(202)	(254)	(1,475)	(426)
Income (loss) before income taxes	6,845	1,397	20,904	(2,933)
Provision for (benefit from) income taxes	459	(124)	1,493	1,167
Net income (loss)	\$ 6,386	\$ 1,521 =======	\$ 19,411	\$ (4,100)
Net income (loss) per share: Basic	\$ 0.18	\$ 0.05	\$ 0.55	\$ (0.13)
Diluted	\$ 0.17	\$ 0.05	\$ 0.52	\$ (0.13)
Shares used to calculate net income (loss) per share: Basic	35,695	31,781	35.036	31,559
Diluted	38,172 =======	33,759	37,443 =======	31,559

# CONNETICS CORPORATION CONDENSED CONSOLIDATED BALANCE SHEETS (IN THOUSANDS) (UNAUDITED)

	DECEMBER 31, 2004	DECEMBER 31, 2003
ASSETS		
Assets:		
Cash, cash equivalents and short-term investments	\$ 72,382	\$114,662
Restricted cash	3,963	304
Accounts receivable and other current assets	25,100	7,408
Soriatane asset, net	120,249	
Property and equipment, net	11,830	5,628
Other long-term assets	12,204	17,895
Total assets	\$245,728	\$145,897
	======	=======
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities and stockholders' equity:		
Current liabilities	\$ 27,388	\$ 10,127
Other liabilities	90,024	90,016
Stockholders' equity	128,316	45,754
Total liabilities and stockholders' equity	\$245,728	\$145,897

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